UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF WISCONSIN

INNOGENETICS, N.V.,

Plaintiff,

vs. Case No. 05-C-0575-C

ABBOTT LABORATORIES,

Defendant.

DEFENDANT'S OPPOSITION TO
PLAINTIFF'S MOTION FOR ENHANCED DAMAGES AND ATTORNEY'S FEES

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PRELIMINARY STATEMENT

Innogenetics argues that Abbott's conduct both prior to and during this litigation warrants an award of enhanced damages and attorneys' fees. But enhanced damages and exceptional case findings are reserved for the truly egregious cases where a party has no evidence with which to make a good faith argument. Here, the evidence shows that, prior to litigation, Abbott conducted a diligent investigation and formed a good faith belief that it did not infringe any valid claim of the patent-in-suit. Likewise, during litigation, Abbott had strong defenses and pursued them in good faith.

As at trial, Innogenetics' argument that Abbott acted in bad faith after learning of a potential issue with the '704 patent is not based on facts and evidence, but rather on unsupported assertions and innuendo. For example, Innogenetics asserts that "Abbott belatedly contrived a tale of reliance on 'opinions' of counsel." In fact, Abbott began investigating long **before** Innogenetics even mentioned the '704 patent and continued to investigate **after** Innogenetics misrepresented that it was "unconcerned with infringement." In the end, Abbott received and relied on no less than **four** opinions of highly qualified patent attorneys, each of whom had Ph.D.'s in the relevant science, that the '704 patent was invalid in light of the Cha PCT Application.

Innogenetics does not attack the substance of the opinions or the qualifications of the attorneys who prepared them. Instead, Innogenetics maintains here, like it did at trial, that these opinions are the result of a secret conspiracy that would have required active participation by, among others, lawyers with unblemished reputations at two publicly traded corporations and a nationally-recognized law firm. But there is absolutely no evidence to support this accusation.

Innogenetics argues that the two Dorsey & Whitney opinions relied on by Abbott are "virtually identical" in substance. But that is not evidence of bad faith. Innogenetics has no

evidence that the Dorsey & Whitney lawyers were instructed to reach the same opinion or that they would have followed any such instruction had there been one. Indeed, all the evidence is to the contrary. Innogenetics also seeks to ridicule the second Dorsey & Whitney opinion by calling it a "dressed up" version of the first Dorsey & Whitney opinion. By "dressed up," Innogenetics apparently refers to the fact the second opinion is more formal than the first. However, there is nothing improper or conspiratorial about Abbott, having first obtained a legal opinion written for sophisticated patent lawyers, later obtaining a more formal opinion for presentation in court after Innogenetics confirmed that it intended to sue.

Beyond its unsupported claims of conspiracy, Innogenetics relies now, as it did at trial, on speculation about the presence of a draft stamp on a copy of the first Dorsey & Whitney opinion and improper inferences about the purported lack of an opinion on the issue of non-infringement. None of this is evidence of bad faith.

Likewise, Innogenetics has no evidence to support its claim of copying. Indeed, at trial, Innogenetics conceded the absence of copying. It had to. The accused products are based on an entirely different platform (realtime PCR with TaqMan probes) than the patented technology. Innogenetics now suggests that targeting of the 5' UTR region proves copying. However, the undisputed evidence, including admissions from the named inventor of the '704 patent, is that use of the 5' UTR region for genotyping HCV had been in the art for years when the accused products were developed, prior to the claimed invention in the '704 patent.

Nor is it true, as Innogenetics states, that Abbott's defenses during litigation had no legal or factual basis. On each of these, Abbott had compelling facts and arguments in its favor.

On the question of noninfringement, for example, the Court's construction required the detection of a complex. Yet Abbott's method does not involve detecting a complex. Indeed, it is undisputed that the only detection - and that is the detection of a *fluorophore* molecule, not a nucleic acid complex - takes place only in the *absence* of the complex. This set of facts alone is enough to establish that there was no literal infringement and no infringement under the doctrine of equivalents.

Abbott's arguments that the '704 patent is invalid were also very well supported. For example, the Cha PCT Application anticipated the '704 patent, and Abbott submitted an element-by-element comparison that showed this to be true. Later, Innogenetics actually stipulated, and the '704 patent's inventor, Dr. Maertens, *admitted* that the '704 patent's use of probes 77 and 78 in the 5' UTR to specifically hybridize was first invented by Cha and disclosed in the Cha PCT Application. Abbott had other good faith arguments about the Cha '693 and Resnick '718 patents, and how they anticipated and/or rendered obvious, the patent-in-suit.

Innogenetics' argument about there being no basis for Abbott to raise a defense of unenforceability due to inequitable conduct ignores the fact that Dr. Maertens *admitted at trial* that Innogenetics' '704 patent claims what Dr. Cha invented and had disclosed in his PCT Application earlier. Dr. Maertens was well aware of these disclosures in Cha PCT Application because of specific statements made by the European Patent Office, and by Innogenetics in response, about them. Yet nothing was ever said to the Patent Office about this overlap in subject matter.

Accordingly, as set forth in detail below, the facts and circumstances of this case do not warrant enhanced damages or an award of attorneys' fees.

ARGUMENT

I. INNOGENETICS IS NOT ENTITLED TO ENHANCED DAMAGES UNDER THE TOTALITY OF THE FACTS AND CIRCUMSTANCES

Innogenetics concedes that a finding of willfulness by the jury is only the first step in determining whether to enhance damages. *Read Corp. v. Portec, Inc.*, 970 F.2d 816 (Fed. Cir. 1992), *abrogated on other grounds*, *Markman v. Westview Inst., Inc.*, 52 F.3d 967 (Fed. Cir. 1999), cited by Innogenetics, holds that "[t]he paramount determination in deciding to grant enhancement and the amount thereof is the egregiousness of the defendant's conduct based on **all the facts and circumstances**." *Id*. at 826 (emphasis added).

That determination must be based on far more than a finding of willfulness. *See Read*, 970 F.2d at 827 (setting forth factors to be considered in determining whether enhanced damages are appropriate). *See also State Indus., Inc. v. Mor-Flo Indus., Inc.*, 948 F.2d 1573, 1576 (Fed. Cir. 1991) ("A finding of willfulness does not by any means compel an award of enhanced damages"). Rather, "[a] finding of willful infringement merely ***authorizes***, but does not ***mandate*** an award of increased damages." *Modine Mfg. Co. v. Allen Group, Inc.*, 917 F.2d 538, 543 (Fed. Cir. 1990) (emphasis in original) (affirming denial of enhanced damages despite finding of willfulness); *see also Transclean Corp. v. Bridgewater Servs., Inc.*, 290 F.3d 1364. 1377-78 (Fed. Cir. 2002) (same); *Oscar Mayer Foods Corp. v. Conagra, Inc.*, 869 F. Supp. 656, 667 (W.D. Wis. 1994) (denying enhanced damages despite finding of willfulness where defendant's challenge on the merits was sufficiently strong and vigorously pursued).

As explained more fully below, the jury's finding of willfulness here is unsupportable. There was no evidence whatsoever to undergird Innogenetics' dark innuendos suggesting a secret conspiracy whose execution would have required the active involvement,

among others, of lawyers with unblemished reputations at two publicly-traded companies and a nationally recognized law firm.[1] In such a case, no enhanced damages can be appropriate.

II. THE JURY'S FINDING OF WILLFULNESS IS CONTRARY TO THE EVIDENCE, AND ANY ENHANCEMENT OF DAMAGES WOULD BE IMPROPER

A. Innogenetics Conceded the Absence of Copying at Trial

The absence of copying is a highly persuasive factor in demonstrating the absence of willfulness. *See Crystal Semiconductor Corp. v. TriTech Microelectronics Intern., Inc.*, 246 F.3d 1336, 1352 (Fed. Cir. 2001); *Advanced Display Sys., Inc. v. Kent State Univ.*, 212 F.3d 1272, 1285 (Fed. Cir. 2000); *The Procter & Gamble Co. v. Paragon Trade Brands, Inc.*, 989 F. Supp. 547, 615 (D. Del. 1997).

At trial, the undisputed *evidence* was that Abbott did not copy the '704 patent. Dr. White, Celera's Chief Scientific Officer, testified that the scientists at Celera independently developed their product and did not copy.[2] Dr. Leckie corroborated that testimony.[3] In its motion, Innogenetics suggests that because Dr. White *read* the '704 patent when it issued years before, Celera necessarily *copied* it.[4] But, there is no basis for such a conclusion. The accused products are based on an entirely different technology platform than the patented technology. They use a realtime instrument manufactured by Applied Biosystems called a Prism 7000

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[1] *See also* Defendant Abbott's Brief in Support of Its Motion For Judgment As Matter of Law, or in the Alternative, Motion For New Trial on Damages and Willful Infringement, 09/22/2006, Dkt. No. 366, at 24-43, which is incorporated herein by reference.

[2] Trial Tr., 9/6/06, v. III, 62:1-66:2; 67:5-17.

[3] *See* Trial Tr., 9/8/06, v. I, 22:22-23.

[4] Innogenetics' Motion for Enhanced Damages and Attorney's Fees, 9/25/06, Dkt No. 372 (hereinafter "Motion"), at 28-29; Declaration of Lissa Koop in Support of Innogenetics' Motion for Enhanced Damages and Attorney's Fees, 9/25/06, Dkt. No. 373, Exs. A & B, "Timeline/Continuum" at June 2002.

System[5] and the TaqMan probes developed by scientists formerly at Cetus (and currently working for Celera), which Celera licensed from Cetus' successor, Roche.[6]

Innogenetics' suggestion that the targeting of the 5' UTR region proves copying is likewise without support. Dr. White testified that Celera chose the 5' UTR sequence by comparing it to others in the publicly available databases--not by reference to the '704 patent.[7] In his deposition, Dr. White explained that it was "obvious to him that the 5' region was suitable for genotyping."[8] Dr. White, a renowned scientist who has written over 80 articles,[9] edited four books on polymerase chain reaction (PCR), and supervised the work of Dr. Kary Mullis, the Nobel prize-winning inventor of PCR,[10] was well qualified to make such a determination. Further, the Resnick '718 patent described using the 5' UTR region,[11] as did the Cha '693 patent and PCT Application.[12] Even Dr. Maertens, the named inventor of the '704 patent, admitted that Innogenetics was not the first to genotype HCV, that it did not discover the 5' UTR region on the HCV, and that it was not the first to discover that probes could hybridize to nucleotide sequences in the 5' UTR region.[13] Thus, the use of the 5' UTR region for genotyping HCV had been in the

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[5] Trial Tr., 9/6/06, v. III, 45:6-10.

[6] Trial Tr., 9/6/06, v. III, 45:11 13; 9/7/06, v. I, 19:7-24.

[7] Trial Tr., 9/6/06, v. III, 61:6-24; 65:4-66:2.

[8] Deposition of Thomas White, 6/8/06, Dkt. No. 112, 31:13-17.

[9] Trial Tr., 9/6/06, v. III, 31:9-14.

[10] Trial Tr., 9/6/06, v. III, 37:1-38:24.

[11] Trial Tr., 8/29/06 v. III, 21:16-22:2; DX 305, '718 patent, Declaration of Gabriel Gross in Support of Abbott's Opposition to Plaintiff's Motion for Enhanced Damages and Attorney's Fees, (hereinafter "Gross Decl."), Ex. 3.

[12] Trial Tr. 8/28/06 v. II, 49:13-24; 8/29/06 v. III, 8:13-9:18; DX 321, Gross Decl., Ex. C; Gross Decl., Ex. D

[13] Trial Tr., 8/30/06, v. III, 45:12-21.

art for years when the accused products were developed, and prior to the invention claimed in the '704 patent.

Not surprisingly, Innogenetics' counsel conceded at trial that there was no evidence to support an allegation of copying: he made no mention of it in his closing argument to the jury[14] and in his rebuttal he conceded it.[15] Innogenetics' attempt to assert copying now, with no supporting evidence, is just one of many examples of the overreaching and misstatement that permeate Innogenetics' motion.

B. Abbott Repeatedly Investigated Innogenetics' Patent and Formed a Good Faith Belief that It Was Invalid and Not Infringed

Innogenetics asserts that Abbott's actions after becoming aware of potential issues with the '704 patent were "inadequate under standards of commercial reasonableness" and were "undertaken in bad faith in order to mislead the jury."[16] In doing so, Innogenetics necessarily asserts that Dr. Ann Pease, Dr. Birgit Millauer and others at the Dorsey & Whitney firm involved in the preparation of the two written opinions on the '704 patent were co-conspirators in an unethical and unlawful agreement with Dr. Lee, Dr. Schodin and Dr. Galloway. Innogenetics implies that they all conspired to provide cover for Abbott by declaring that, in their judgment, the '704 patent was invalid. Thus, when asked at trial who had provided the opinion that the '704 patent was invalid, they could each stand up and, in the words of Innogenetics' counsel, declare: "I'm Spartacus."

Innogenetics' innuendo-laden argument cannot be considered credible given the complete absence of evidence to support it. Instead, Innogenetics asked the jury to speculate that

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[14] Trial Tr., 9/8/06, v. III, 17:4-32:5.

[15] Trial Tr., 9/8/06, v. III, 62:3-62:19.

[16] Motion, at 7.

Abbott and Celera had calculated that a Belgian company would never bring an expensive patent action in the United States. But, the undisputed evidence was that Abbott did not even suspect that an infringement action might be in the works until March 2005--long after Dr. Pease, Dr. Millauer, Dr. Lee, Dr. Schodin and Dr. Galloway had all weighed in on invalidity. Regardless, Innogenetics fails to cite any authority to support its claim that Abbott failed to meet standards of "commercial reasonableness" and relies entirely on innuendo and unsupported assertions to make its claim of bad faith. That is because controlling case law and the actual facts lead to but one conclusion--that Abbott's actions far exceed that of a responsible "corporate citizen" acting in good faith.

The test for willful infringement is "whether, under all of the circumstances, a reasonable person would prudently conduct himself with any confidence that a court might hold the patent invalid or not infringed." *Minnesota Mining & Mfg. Co. v. Johnson & Johnson Orthopedics, Inc.*, 976 F.2d 1559, 1580 (Fed. Cir. 1992). It is well established that when a defendant reasonably relies on a competent opinion of counsel, a finding of non-willfulness usually results. *See Read Corp.*, 970 F.2d at 828-829 ("Those cases where willful infringement is found despite the presence of an opinion of counsel generally involve situations where opinion of counsel was either ignored or found to be incompetent."). To reasonably rely on the opinions of counsel, the opinions need not be ultimately correct. *See Ortho Pharm. Corp. v. Smith*, 959 F.2d 936, 944 (Fed. Cir. 1992) ("While an opinion of counsel letter is an important factor in determining the willfulness of infringement, its importance does not depend upon its legal correctness."); *Read Corp.*, 970 F.2d at 830 ("That counsel's opinion turned out to be contrary to our judgment with respect to the '194 patent does not make his advice regarding the patent incompetent."). In *Read*, the appellate court overturned a finding of willfulness because the

defendant relied on two written opinions of counsel, engaged in numerous conversations with counsel, and the defenses asserted in the litigation tracked those discussed in the opinions.[17]

Here, Abbott relied on no fewer than four opinions of highly qualified patent attorneys, from Dr. Schodin, from Dr. Galloway, and two from Dorsey & Whitney. The reasonableness of these opinions was confirmed by Dr. Bruce Patterson, a Stanford University virologist, who opined at trial that the '704 patent was invalid. Although the jury ultimately determined on the record before it that those opinions were incorrect, there was no testimony whatever that the opinions of counsel were bad or Abbott should have recognized them as such.

1. Dr. David Schodin analyzed the '704 patent and concluded it was invalid

Innogenetics claims that Abbott was "expressly informed of potential issues with Innogenetics' patents in September of 2003."[18] Innogenetics cites to a letter dated September 22, 2003 from its Director of Intellectual Property & Licensing, Kevin Nachtrab, to Abbott's Business Manager, Dr. Gene Cartwright.[19] However, that letter makes no mention of the '704 patent at issue in this lawsuit. Rather, the letter focused solely on Innogenetics' '244 patent, which had issued on April 15, 2003. Even as to that patent, Innogenetics did not claim infringement, but rather states only that "you may wish to review the '244 patent for its relevance

[17] Although the Dorsey & Whitney written opinions only specifically addressed infringement with respect to *some* claims, Dr. Galloway advised Abbott's President, Ed Michael, that there were non-infringement defenses, (Trial Tr., 9/7/06, v. III, 21-22), and Mr. Michael relied on that advice. (Trial Tr., 9/7/06, v. III, 26:5-14.) Dr. Schodin also advised Mr. Michael that there were non-infringement defenses. (Trial Tr., 9/7/06, v. III, 13:9-13.) Mr. Michael relied on Dr. Schodin as a patent lawyer "with a good deal of experience" and an "informed basis for rendering an opinion." (Trial Tr., 9/7/06, v. III, 14:7-25.)

[18] Motion, at 8.

[19] DX. 509, Gross Decl, Ex. E.

to your activities" and that "Innogenetics is prepared to discuss licensing of the '244 patent with interested parties."[20]

Abbott did not ignore the letter. Nor did it direct its attorneys to obtain an opinion of non-infringement or otherwise instruct them to come up with the "right answer." To the contrary, Dr. Cartwright asked Abbott's in-house patent attorney, Dr. David Schodin, who holds a Ph.D. in the relevant science, to "look into whether or not it will be desirable to seek a license to the Innogenetics' patent."[21] Dr. Schodin immediately undertook an analysis of not only the one patent mentioned in Innogenetics letter, but also three other Innogenetics patents that were not mentioned, including the '704 patent.

As it did at trial, Innogenetics mischaracterizes Dr. Schodin's December 28, 2003 email to Dr. Cartwright in which Dr. Schodin reports his "initial level analysis."[22] Dr. Schodin did not, as Innogenetics claims, indicate that "Abbott infringed the '704 patent."[23] Rather, in his email, which addresses the four Innogenetics' patents collectively and none of them individually, Dr. Schodin makes clear that "[w]e have not completed enough analysis to recommend opening licensing negotiations" and that "we expect to have reportable results in January, hopefully early January."[24] Likewise, while Dr. Schodin states that "this initial analysis suggests that it will probably be desirable to seek an HCV license from Inno," he makes clear that "this suggestion is not a conclusion."[25] Indeed, Dr. Schodin specifically states that further analysis is required to

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[20] *Id.*

[21] Trial Tr., 9/6/06 v. I, 41:7-14.

[22] PX 1046; Gross Decl. Ex. F; Trial Tr., 9/6/06 v. I, 41:7-14.

[23] Motion, at 14.

[24] PX 1046; Gross Decl. Ex. F.

[25] *Id.*

determine whether "special meaning" of claim terms of the patents "place the Alliance products outside the scope of the claims" and that "[i]t is likely . . . that the US Patent Office overlooked significant prior art disclosures relevant to HCV genotyping, and that sound invalidity arguments relating to the broader patent claims can be made."[26]

It is undisputed that Dr. Schodin did conduct a further analysis. He personally reviewed the Cha PCT Application along with several other references and reached the conclusion that the '704 patent was invalid because "Dr. Cha had, in fact, performed a method of genotyping as described in the [Innogenetics'] patent."[27] It is also undisputed that Dr. Schodin communicated his invalidity conclusion to the Abbott management team.[28]

Significantly, Innogenetics has never offered (and could not offer) any evidence that Dr. Schodin was not well qualified by education and experience to understand both the scientific and legal issues involved. Nor has Innogenetics offered any evidence that Dr. Schodin's analysis was incompetent or unreasonable. Thus, Abbott could safely have relied only on Dr. Schodin's opinion. *See Western Elec. Co. v. Stewart-Warner Corp.*, 631 F.2d 333, 337 (4th Cir. 1980) ("Just because an attorney is in-house counsel does not mean that his opinions are necessarily suspect.").

2. <u>Dorsey & Whitney analyzed the '704 patent and concluded it was invalid and not infringed</u>

Abbott could have relied only on Dr. Schodin's opinion, but did not. Again, before Innogenetics even mentioned the '704 patent, Abbott, in consultation with Celera, chose a nationally-recognized law firm, Dorsey & Whitney, to provide an independent analysis of the

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[26] *Id.*

[27] Trial Tr., 9/6/06 v. I., 73:9-75:3.

[28] Trial Tr., 9/6/06 v. I, 75:19-76:1.

'704 patent.[29] In March 2004, after thoroughly analyzing the '704 patent and several others, Dorsey & Whitney provided a thirty-six page written memorandum (not including lengthy appendices detailing Dorsey & Whitney's nucleic acid sequence analysis) documenting its opinion that independent claim 1 and dependent claims 2-7 were determined to be invalid and dependent claims 8-13 not infringed.[30]

Innogenetics has presented no evidence that the attorneys who prepared the March 2004 opinion were not competent to do so. Nor could it. Indeed, the undisputed evidence is that the two principal authors--Dr. Birgit Millauer and Dr. Anne Pease--were both imminently qualified patent attorneys who, like Dr. Schodin, have Ph.D.'s in the relevant science.[31] Likewise, Innogenetics has not offered a shred of evidence that these two lawyers at a well-respected national patent law firm would risk their professional reputations by supplying an opinion that they knew to be unreasonable or unsupported and has not offered any plausible motive for why they would do so.

Instead, Innogenetics must resort to distorting Dr. Millauer's deposition testimony to argue that she was unwilling to vouch for the sufficiency of the opinion.[32] However, Dr. Millauer made clear her belief that the conclusions memorialized in the written opinion and the underlying analysis certainly could be reasonably relied upon. When asked at her deposition if the written memorandum was sufficient by itself to provide a basis for reliance, she said "I believe that our oral communication, conclusions of which are reflected in the memorandum,

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[29] Trial Tr., 9/6/06 v.I, 38:22-39:10; Trial Tr., 9/7/06 v. I, 45:22-48:5.

[30] DX 625; Gross Decl., Ex. G; Trial Tr., 9/7/06 v. I, 48:10-50:21.

[31] Deposition of Birgit Millauer, 08/24/06, Dkt. No. 284, 7:14-22; 8:12-9:19, 15:5-16; Deposition of Victor Lee, 8/23/06, Dkt. No. 287, 34:2-16.

[32] Motion, at 10.

provide that basis."[33] She further clarified, following the ellipses in Innogenetics' motion, that "this memorandum was not created in a vacuum. It was created as, you know, as an outline of the results of our analysis, and it was eventually put into formal final form."[34]

Similarly, Innogenetics' litany of purported reasons why the March 2004 Dorsey & Whitney opinion "could not have been relied on in good faith by any sophisticated patent lawyer" does not withstand scrutiny. For example, Innogenetics criticized the March 2004 opinion document because it:

- Lacked an opinion on infringement of many claims. ***But the March 2004 written opinion did include non-infringement opinions as to claims 8-13 and Dr. Millauer gave oral opinions as to the others.***[35] ***That the March 2004 written opinion does not include a non-infringement opinion as to claims 1-7 in no way renders it incompetent or unreliable. Indeed, the Court properly instructed the jury that "Innogenetics must prove that Abbott proceeded or continued with activities that the Court has found to constitute infringement with a good faith belief that the patent was <u>either</u> invalid, unenforceable, or not infringed."***[36]
- Relied on single reference. ***There is nothing improper about relying a single reference--that is the very definition of anticipation.***[37]
- Was silent on enablement. ***As one skilled in the relevant art at the time of the alleged invention, Dr. Millauer was well suited to determine, as***

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[33] Millauer Depo., 08/24/06, Dkt. No. 284, 137:1-3.

[34] *Id.*, 138:16-20.

[35] DX 625, Gross Decl., Ex. G, at 3-13; Trial Tr., 9/6/06, v. I, 44:20-23; Millauer Depo., 08/24/06, Dkt. No. 284, 129:20-131:2.

[36] Jury Instructions - Damages, 9/11/06, Dkt. No. 359, at 4 (emphasis added.); Trial Tr., 9/8/06, v. III, 69:25-70:4. Indeed, Innogenetics' repeated arguments regarding the alleged "failure" of the written Dorsey & Whitney opinions to discuss infringement were both improper and prejudicial. *See* Defendant Abbott's Brief in Support of Motion for Judgment as Matter of Law, or in the Alternative, Motion for New Trial on the Issues of Damages and Willful Infringement, 09/22/2006, Dkt. No. 366, at 25, which is incorporated herein by reference.

[37] Trial Tr. 8/31/06, v. II, 124:13-14 (Jury inst.: "To anticipate a claim, each and every element in the claim must be present in a single item of prior art.")

she did, that the Cha PCT Application taught how to perform the claimed methods of genotyping.[38]

- Did not outline legal standards for invalidity. ***As Innogenetics concedes, the March 2004 opinion was written for "sophisticated patent lawyers" – its intended audience was well versed in the law regarding invalidity and infringement.***[39]

- Did not identify any conversations with persons of skill in the relevant art. ***Dr. Millauer testified at deposition that she had such conversations, she just didn't memorialize them in the written opinion.***[40] ***Further Drs. Millauer and Pease, the principal authors, are themselves persons of skill in the relevant art.***[41]

- Did not discuss claim construction. ***Dr. Millauer testified that she discussed claim construction with Dr. Schodin.***[42]

- Had no analysis of the file history. ***Dr. Millauer testified that she reviewed the file histories.***[43]

The fact that the first opinion, written before Innogenetics had even mentioned the '704 patent to Abbott, was not prepared as a formal opinion to be presented in court, in no way renders the opinion or the underlying analysis unreliable or incompetent. As Dr. Millauer explained, the memorandum was not "created in a vacuum" but rather was provided in connection with numerous oral communications regarding that analysis with individuals at Abbott and Celera, all of whom Innogenetics concedes are "sophisticated patent lawyers."

Innogenetics is well aware of the work Dr. Millauer performed in reaching her opinion because she testified about it at deposition. While Innogenetics succeeded in excluding

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[38] Millauer Depo., 08/24/06, Dkt. No. 284, 172:12-23; 183:20-184:1.

[39] Trial Tr., 9/6/06, v. I, 48:1-3.

[40] Millauer Depo., 08/24/06, Dkt. No. 284, 99:5-101:6.

[41] Millauer Depo., 08/24/06, Dkt. No. 284, 7:14-22; 8:12-9:19, 15:5-16; Lee Depo., 8/23/06, Dkt. No. 287, 34:2-16.

[42] Millauer Depo., 08/24/06, Dkt. No. 284, 129:20-132:7; 132:19-133:7.

[43] Millauer Depo., 08/24/06, Dkt. No. 284, 48:8-25.

Dr. Millauer's testimony at trial, it is disingenuous for Innogenetics to suggest in the present motion that this work was never performed.[44]

Notably, at trial, Innogenetics did not challenge the conclusion of the March 2004 opinion or its underlying analysis as incompetent or unreasonable. Indeed, Abbott's anticipation defense at trial tracked the analysis and conclusion of the Dorsey & Whitney opinion. The Court denied Innogenetics' JMOL on anticipation by the Cha PCT Application at the close of evidence, recognizing that a reasonable jury could find the '704 patent invalid in light of the Cha PCT Application. That alone undercuts any argument that Abbott's reliance on the opinion was unreasonable.

3. Dr. Norval Galloway analyzed the '704 patent and concluded that it was invalid

In December 2004, Innogenetics sent a second letter to Abbott identifying four patents including, for the first time, the '704 patent. Like Innogenetics' first letter, this letter made no mention of infringement and again merely states that "you may wish to review these patents for their relevance to your activities" and that "Innogenetics is prepared to discuss licensing of these and other patents within its considerable HCV portfolio with interested parties."[45] Indeed, when Dr. Norval Galloway, Abbott's in-house patent attorney, contacted

[44] Likewise, Innogenetics' argument at trial that the Dorsey & Whitney opinions were unreliable because there were authored by "this lawyer who didn't show up in this Courtroom" (9/8/06, v. III, 21:22-24) was improper and prejudicial. *See* Defendant Abbott's Brief in Support of Motion for Judgment as Matter of Law, or in the Alternative, Motion for New Trial on the Issues of Damages and Willful Infringement, 09/22/2006, Dkt. No. 366, at 42-43, which is incorporated herein by reference.

[45] PX 1047; Gross Decl. Ex. H.

Innogenetics in response to the letter, Innogenetics affirmatively misrepresented that it was "unconcerned with infringement."[46] But Abbott investigated further anyway.

In response to the second letter, Gene Cartwright asked Dr. Galloway, an Abbott in-house patent attorney, to look at the issue and advise as to whether Abbott should seek a license.[47] There is no dispute that Dr. Galloway was also thoroughly competent to render such an opinion. Indeed, in closing argument, Innogenetics' counsel acknowledged that Dr. Galloway is "careful, intelligent, sophisticated."[48] Dr. Galloway conducted his own analysis of the Cha PCT Application, interviewed a number of persons and reviewed the March 2004 Dorsey & Whitney opinion. He reached the same conclusions concerning patent invalidity and communicated them to management.[49]

4. Dorsey & Whitney investigated the '704 patent a second time and again concluded that it was invalid and not infringed

When Innogenetics threatened, for the first time, in March of 2005 to sue for infringement, Abbott retained Dorsey & Whitney to provide a more formal written opinion.[50] In response, Dorsey & Whitney provided a detailed 71-page opinion of counsel that again reached the conclusion that the '704 patent was invalid. Innogenetics did not attack the substance of the second written opinion at trial and does not now. Instead, Innogenetics notes that the second

[46] Trial Tr., 9/6/06 v. II, 64:10-16.

[47] Trial Tr., 9/6/06 v. II, 19:25-21:19.

[48] Trial Tr., 9/8/06, v. III, 26:25-27:4.

[49] Trial Tr., 9/6/06, v. III, 7:11-12, 25:21-28:2; 9/7/06, v. III, 27:16-18.

[50] Deposition of Norval Galloway, 08/22/06, Dkt. No. 286, 144:14-18; Trial Tr. 9/6/06, v. III, 19:20-20:7.

Dorsey & Whitney written opinion is "virtually identical" in substance to the first Dorsey & Whitney opinion.[51]

Just as it did in front of the jury, Innogenetics attempts to turn evidence of good faith--two opinions from a well-respected patent law firm--into something sinister. Innogenetics conveniently ignores (and asks this Court to close its eyes to the fact) that Dorsey & Whitney's original opinion was rendered months before Innogenetics even raised the '704 patent. Without any proof, Innogenetics then asks the Court to believe that lawyers at Dorsey & Whitney, Abbott and Celera set aside their integrity, reputations and obligations as officers of the court, and conspired to produce not one, but four opinions. Because this was not the case, there is absolutely no evidence to support this accusation. Indeed, all the evidence is to the contrary.[52]

Innogenetics also seeks to attack the second written Dorsey & Whitney opinion by claiming that it shares virtually all of the same so-called "deficiencies" that it attributes to the first written opinion. That claim is simply false. Among other things, the second written Dorsey & Whitney opinion includes a detailed discussion of the legal standards for non-infringement and invalidity, a lengthy discussion of the prosecution history of '704 patent and related patents, and a proposed claim construction of key patent terms.[53]

Finally, Innogenetics argues that the second Dorsey & Whitney opinion is nothing more than a "dressed up" version of the March 2004 opinion "cynically calculated to fool a lay jury." By "dressed up," Innogenetics apparently refers to the fact that the second opinion does indeed more fully document such things as the relevant legal standards, the prosecution history

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[51] Motion, at 12-13.

[52] Trial Tr., 9/6/06, v. II, 68:11-69:7.

[53] See, e.g., DX 609, Gross Decl., Ex I.

and counsel's proposed claim construction. However, there is nothing improper or out of the ordinary about a party who has obtained an opinion of counsel later seeking another, more formal opinion after a patent holder confirms that it intends to sue. It was Innogenetics who sought to "fool a lay jury" (and this Court) by arguing otherwise.[54]

C. Innogenetics Adduced No Evidence of Willfulness

The record reflects that Innogenetics never introduced any competent evidence of willfulness. For a reasonable jury to find willfulness, Innogenetics had to:

- Offer an admission by an insider at Abbott that the decision makers did not have a good-faith belief that the '704 patent was invalid and, therefore, not infringed--***but everyone testified to the contrary.***
- Introduce evidence of copying--***but as set forth above, the sole evidence was that the Celera product development team developed the accused products by itself, without reference to the patent, and that the accused products are based on an entirely different platform than the patented technology.***
- Show that Abbott has a policy or practice of not paying license fees--***but the evidence was that Abbott has entered into four licenses for the two accused products.***[55]
- Show that Abbott instructed its attorneys to come up with the "right answer" or directed them to obtain an opinion of non-infringement--***but a small army of lawyers with unblemished reputations and unquestioned competence all concluded that the '704 patent was invalid.***
- Show that the opinions Abbott obtained were prepared by attorneys incompetent to render them or that the opinions were obviously

[54] In addition to the evidence summarized above, there was considerable evidence further demonstrating Abbott's good faith that the jury was improperly precluded from hearing or considering. *See* Defendant Abbott's Brief in Support of Motion for Judgment as Matter of Law, or in the Alternative, Motion for New Trial on the Issues of Damages and Willful Infringement, 09/22/2006, Dkt. No. 366, at 35-43, which is incorporated herein by reference. Even without such evidence, the clear weight of the evidence is against the jury's finding of willfulness and, in any event, does not warrant an award of enhanced damages.

[55] Trial Tr., 9/7/06, v. II, 37:23-38:13, 49:21-50:1.

unrealistic--***but Drs. Pease, Millauer, Lee, Galloway and Schodin were all impeccably qualified to render their opinions.***

- Show that Abbott ignored warnings that it was infringing--***to the contrary, Innogenetics affirmatively misrepresented that it was "unconcerned with infringement."***[56] ***Nevertheless, Abbott investigated anyway.***

D. <u>"Draft" Or Not, It Is Undisputed that Abbott Received Dorsey & Whitney's First Opinion in March 2004</u>

Lost in Innogenetics' lengthy speculation concerning the presence of a "draft" stamp on Dr. Lee's copy of the 2004 written Dorsey & Whitney opinion is the undisputed fact that *Abbott received Dorsey & Whitney's written opinion in March 2004*. Dr. Lee, Celera's in-house patent counsel, testified he forwarded the report to Dr. Schodin,[57] and Dr. Schodin testified that received it and read it.[58] The Dorsey & Whitney bill reflected that Dr. Schodin participated in at least three telephone calls, one lasting over three hours, with Dorsey & Whitney to discuss the opinion.[59] Dr. Schodin testified that he closely tested the 2004 opinion during those conversations.[60] Further, Dr. Lee, who participated in those conversations, corroborated that they occurred.[61]

Innogenetics points to Dr. Galloway's testimony that Dr. Lee had reported in a voicemail message almost a year later that he had not provided a "detailed" opinion of counsel to Dr. Schodin. Even if Dr. Lee did not misspeak and Dr. Galloway did not mishear, Dr. Lee may

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[56] Trial Tr., 9/6/06, v. II, 64:10-16.

[57] Trial Tr., 9/7/06 v. I, 50:12-14.

[58] Trial Tr., 9/6/06 v. I, 44:10-17.

[59] Trial Tr., 9/6/06, v. I, 5:1-7.

[60] Trial Tr., 9/6/06, v. II, 5:9-12; 9/7/06, v. I, 4:19-5:12; Deposition of David Schodin, 8/24/06, Dkt. No. 285, 91:5-92:22.

[61] Trial Tr., 9/7/06, v. I, 51:2-7.

have meant only that he had not provided Dr. Schodin a lengthy and more complete opinion letter, as was later provided in 2005.

Dr. Schodin further testified that he did not destroy the March 2004 written memorandum.[62] Nor would he have had any reasons to. It is evidence of Abbott's investigation and good faith belief. Thus, it is irrelevant – and certainly not evidence of "bad faith" – that a maintenance employee apparently lost many of Dr. Schodin's files, including his written copy of the 2004 opinion letter, following Dr. Schodin's resignation from Abbott. Innogenetics' reliance on *nCube Corp. v. SeaChange Int'l, Inc.*, 436 F.3d 1317 (Fed. Cir. 2006) for the proposition this is somehow evidence of "bad faith" is misplaced. The finding of willfulness in that case did not, as Innogenetics suggests, turn on so-called "shoddy file management." Rather, the court held that the finding of willfulness was supported by, among other things, defendant's deliberate failure to supply "at least one important technical document" to opinion counsel. *nCube Corp.*, 436 F.3d at 1324 ("SeaChange manipulated the information given to counsel to ensure an opinion of non-infringement."). There was no such evidence here.

Finally, there is no support for Innogenetics' speculation that Dr. Lee instructed someone to send the March 2004 opinion to Dr. Galloway with the "draft" stamp because he knew it was not an appropriate opinion on which either Celera or Abbott could reasonably rely.[63] Nor is the presence of the "draft" stamp "unexplained" as Innogenetics suggests. Dr. Millauer testified at her deposition that the "draft" stamp appeared to be a Dorsey & Whitney stamp[64] and its application by Dorsey & Whitney is entirely consistent with Dr. Millauer's testimony that the

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[62] Schodin Depo., 8/24/06, Dkt. No. 285, 103:12-14.

[63] Motion, at 10.

[64] Millauer Depo., 08/24/06, Dkt. No. 284, 111:24-112:4.

March 2004 written opinion memorandum was created "as an outline of the results of our analysis, and it was eventually put into formal final form."[65]

E. Innogenetics Has Deliberately Mischaracterized Abbott's Waiver of the Attorney-Client Privilege As "Selective"

As the Court is more than well aware by now, while Abbott waived the attorney-client privilege completely, non-party Celera honored the waiver to the extent of the parties' joint-defense privilege but otherwise asserted its rights under *In re EchoStar Commc'ns Corp.*, 448 F.3d 1294 (Fed. Cir. 2006). Thus, when Innogenetics asks that Abbott be punished for a "selective" waiver of the privilege, it is asking that the Court sanction Abbott for non-party Celera's decision to preserve and protect its attorney-client privilege rights. Not surprisingly, Innogenetics cites no authority for the proposition that a party may be sanctioned for the conduct of a non-party, much less authority for the proposition that a party may be sanctioned for the perfectly appropriate assertions of the privilege by a non-party.

III. ABBOTT HAD STRONG NONINFRINGEMENT ARGUMENTS THAT IT HAD EVERY RIGHT TO BRING TO THE JURY, AND WOULD HAVE, WERE IT NOT FOR THE COURT'S IMPROPER ENTRY OF JUDGMENT OF LITERAL INFRINGEMENT AGAINST IT

Innogenetics' brief first rewrites history on the infringement issue. It argues that Abbott should be punished for pursuing its infringement case up to trial because it "was apparent [after the Court's claim construction] that Abbott had no infringement defense."[66] According to Innogenetics, Abbott's stubborn refusal to "concede the obvious . . . greatly increas[ed] the administrative burden on the Court and the litigation costs that had to be borne by

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[65] Millauer Depo., 08/24/06, Dkt. No. 284, 138:18-20.

[66] Motion, at 2.

Innogenetics."[67] Innogenetics completes its fanciful rendition with the utterly false statement that Abbott "drop[ped]" its infringement defense.[68]

The true facts, however, tell a very different story.[69]

A. The Facts Show That Abbott Had Good Faith Arguments That Its Accused Method Did Not Literally Infringe The Patent-In-Suit

First, Abbott did have a non-infringement defense – a very good non-infringement defense. As set forth in more detail in Abbott's motion for new trial,[70] there was no legal or factual basis in the record for a determination that the claims of the '704 patent, as construed by the Court, literally encompass Abbott's accused method as a matter of law.

In its ruling on summary judgment, the Court construed the limitation in Claim 1, "detecting a complex as formed," as "detecting a complex that is or has been formed."[71] The Court did not interpret the meaning of the limitations "with said probe and said nucleic acids of HCV" and did not construe the term "complex" to mean anything other than "complex."[72]

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[67] Motion, at 2.

[68] Motion, at 24.

[69] Notably, Innogenetics vigorously argues that Abbott engaged in bad faith by pursuing meritorious defenses and counterclaims, but ignores the fact that it pursued multiple infringement claims it later dropped - *on the eve of trial*. (*See* Abbott's Notice of Withdrawal of Claims, 8/25/06, Dkt. No. 276.) Further, Innogenetics refused to execute a covenant not to sue along the lines mandated by the Federal Circuit in *Fort James Corp. v. Solo Cup Co.*, 412 F.3d 1340 (Fed. Cir. 2005), with respect to the unasserted claims. Thus, Abbott was required to pursue its declaratory relief counterclaims for invalidity of these claims at trial or lose that defense in the event of future assertion. That Innogenetics waited until the eve of trial to announce it was only going to pursue 3 of the 13 claims in the '704 patent certainly drove up the cost of this case for Abbott and the Court.

[70] Abbott incorporates by reference herein the arguments and facts presented in Abbott's Brief In Support Of Motion For New Trial On The Issues Of Infringement and Invalidity, 9/22/06, Dkt. No. 364, at 10-19.

[71] Opinion and Order, 8/11/08, Dkt. No. 218, at 31.

[72] Opinion and Order, 8/11/08, Dkt. No. 218, at 31.

The Court also found that "[u]sing the accused reagents for genotyping causes the destruction of the complexes formed between the probes and the nucleotides of the HCV target,"[73] that "[t]he destruction of the complex produces a liberated dye molecule that can be detected,"[74] and that "the reporter dye . . . fluoresce[s and that this] fluorescence . . . is [what is] detected."[75] These facts about the accused method were undisputed, having been admitted by Innogenetics itself;[76] Innogenetics' expert witness;[77] and one of the '704 patent's inventors, Dr. Rossau.[78]

A claim is literally infringed only if every claim limitation "exists in the accused product or process just as it is described in the claim language," as construed by the court. *See* Federal Circuit Bar Model Patent Jury Instruction 8.2; *see also Cole v. Kimberly-Clark Corp.*, 102 F.3d 524, 532 (Fed. Cir. 1996) ("Literal infringement of a claim exists . . . when the properly

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[73] Opinion and Order, 8/11/08, Dkt. No. 218, at 10.

[74] Opinion and Order, 8/11/08, Dkt. No. 218, at 10.

[75] Opinion and Order, 8/11/08, Dkt. No. 218, at 9-10.

[76] Innogenetics' Responsive Proposed Finding of Fact, 6/6/06, Dkt. No. 74, ("RPFF") Fact No. 76: "Abbott's products utilize Realtime PCR, which involves destroying any complex formed between a probe and nucleic acids of HCV; what is detected is a cleaved fluorophore, not a complex"). Although this point was undisputed, and was an unqualified admission by Innogenetics, the Court allowed it some wiggle room by allowing it to insert an "Abbott asserts that" before the statement just a couple of weeks before trial. Opinion and Order, 8/11/08, Dkt. No. 218, at 2-4. *See also* RPFF Fact Nos. 73, 79; and RPFF at pp 9-11, 14, 15-16, leaving as "undisputed" Abbott Proposed Fact Nos. 29-38, 46, 48.

[77] Innogenetics' own expert had acknowledged that the complexes transiently formed by the accused reagents are destroyed during the PCR process, and that a liberated dye molecule is subsequently detected. Expert Report of William S. Reznikoff, 4/21/06, Dkt. No. 38, at 10, 18.

[78] Dr. Rossau admitted that the probe/target complexes are destroyed when using TaqMan reagents: (Q. "So is it the case that the fluorophore is not released until the probe is destroyed, the probe hybrid complex is destroyed?" A. "Yes, that's what I said. So only if the hybrid is formed, the probe can be destroyed, and it – and if it is destroyed, this means that a hybrid has been formed"). Deposition of Rudi Rossau, 3/24/06, Dkt. No. 85, 151:12-21, 152:2-9.

construed claim reads on the accused device exactly.") All of Innogenetics' claims, as construed by the Court, require a step of "detecting a complex," and it is undisputed that in the accused method, the complex has been destroyed at the time of detection. Thus, what is detected is the fluorescence that results from the destruction of the complex. On this basis alone, Abbott had more than a good faith, or good, argument that it did not literally infringe; it should have been granted summary judgment on literal infringement. So Abbott certainly was well within its rights to bring the issue to the jury. Had it gone to the jury, Abbott would have presented the testimony of Dr. Patterson, who would have explained how the accused reagents work and why that is very different from "detecting a complex."[79]

In addition, Abbott had Innogenetics' Dr. Rossau's admission that the technology used in Abbott's accused method was neither used by Innogenetics, nor in the state of the art in 1992 when the patent application was filed:

> So at the time when we made our first HCV genotyping LiPA, we didn't use realtime PCR at Innogenetics because it was not state of the art at that time.[80]

Because, by Innogenetics' own inventor's admission, Abbott's accused method lay in the future, Innogenetics could not have claimed it within the scope of its '704 patent coverage.

It is well established that a patent applicant cannot cut off further innovation by claiming subject matter that has yet to be invented. *Fiers v. Revel*, 984 F.2d 1164 (Fed. Cir. 1993). In that case, the court articulated that a patentee may not claim an invention in overly

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[79] Non-Infringement Opinion of Bruce K. Patterson, M.D. Regarding Innogenetics, N.V.'s U.S. Patent No. 5,846,704, and Responses to The Reports of William S. Reznikoff, PhD. and Howard J. Worman, M.D., 5/2/06, Dkt. No. 39, ("Patterson Non-Infringement Expert Report"), at 5-9.

[80] Abbott Laboratories' Responses to Plaintiff's Responsive Proposed Findings of Fact, 6/16/06, Dkt. No. 101, ¶ 78; Rossau Depo, 3/24/06, Dkt. No. 85, 123:5-8.

broad, generic terms that do not comport with the state of the art at the time the application was filed. *Id.* at 1171. To do so would be "an attempt to preempt the future before it has arrived." *Id.*

This ban on claiming future technologies is a fundamental principle in claim construction. In fact, just after trial ended, the Federal Circuit reaffirmed this central principle: that the literal scope of a claim term is limited to what it was understood to mean *at the time of filing*. *See The Massachusetts Inst. of Tech., et al. v. Abacus Software, et al.*, --- F.3d ---, Nos. 05-1142, -1161, -1162, -1163 2006 WL 2613439 (Fed. Cir., Sept. 13, 2006) ("*MIT*"), slip op. at 12-13, n.3 (citing, *inter alia*, *Kopykake Enters., Inc. v. Lucks Co.*, 264 F.3d 1377, 1383 (Fed. Cir. 2001) ("[T]he literal scope of the term is limited to what it was understood to mean at the time of filing."). *See also Bayer AG v. Biovail Corp.*, 279 F.3d 1340, 1348 (Fed. Cir. 2002) ("To construe the meaning of [a disputed claim term] a court must consider *what was known* to one of ordinary skill in this art ….") (emphasis added); *SuperGuide Corp. v. DirecTV Enters., Inc.*, 358 F.3d 870, 879 (Fed. Cir. 2004); *Schering Corp. v. Amgen Inc.*, 222 F.3d 1347, 1353-54 (Fed. Cir. 2000). "This task requires the court to place the claim language in its proper technological *and temporal* context." *SmithKline Beecham Corp. v. Apotex Corp.*, 403 F.3d 1331, 1338 (Fed. Cir. 2005) (emphasis added); *Aquatex Indus., Inc. v. Techniche Solutions*, 419 F.3d 1374, 1380 (Fed. Cir. 2005) (noting claims should be interpreted as they "would be understood by 'a person of ordinary skill in the art in question *at the time of the invention, i.e.*, as of the effective filing date of the patent application.'") (quoting *Phillips v. AWH Corp.*, 415 F.3d 1303, 1313 (Fed. Cir. 2005) (en banc)).[81]

[81] Innogenetics' counsel's reaction to these last three cases was that they were "claim construction" and not infringement cases. (Trial Tr. 8/28/06, v. I, 59:1-5.) Of course, claim (footnote continued)

Abbott raised this issue with the Court and requested the following revision to the jury instructions: "[A] product or method cannot literally infringe a patent claim if that product or process includes elements that were not known or available to one of ordinary skill at the time the patent application was filed."[82]

The Court refused to insert the revision, in part based on Innogenetics' counsel's own disingenuous argument that he had never seen such a proposition in 25 years.[83] Indeed, the record reflects that the Court followed Innogenetics' lead and found infringement despite its understanding that realtime PCR, an important part of Abbott's technology, was a technology that did not exist until after the patent issued:

> THE COURT: -- it infringes the patent because the specifications talk about ***new things*** that come along, ***new ways*** of doing this research, and one of them is realtime came along, you know, pretty soon ***after that patent issued.***[84]

But just because the Court adopted plaintiff's uninformed view does not mean that Abbott, with solid Federal Circuit precedent and an unrebutted admission by one of the inventors of the patent-in-suit that its technology was not in the state of the art in 1992, did not have a good faith basis to present its non-infringement defense to the jury.

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construction is the first part of any infringement analysis. *Markman v. Westview Instruments, Inc.*, 53 F.3d 967, 976 (Fed. Cir. 1995). Because these basic claim construction principles were not applied in this case, the Innogenetics inventors were deemed to have claimed technologies they could not have contemplated, much less invented.

[82] Defendant Abbott Laboratories' Revised Proposed Jury Instructions – Liability, 8/28/06, Dkt. No. 292 at 18 (citing *Aquatex Indus., Inc. v. Techniche Solutions*, 419 F.3d 1374, 1380 (Fed. Cir. 2005); *SmithKline Beecham Corp. v. Apotex Corp.*, 403 F.3d 1331, 1338 (Fed. Cir. 2005); *Bayer AG v. Biovail Corp.*, 279 F.3d 1340, 1348 (Fed. Cir. 2002).

[83] Trial Tr., 8/28/06, v. I, 58:14-25.

[84] Trial Tr., 8/28/06, v. I, 72:2-16 (emphasis added).

B. The Doctrine Of Equivalents Could Not Have Been Used By Innogenetics To Establish Infringement

For the reasons set forth above, Abbott clearly had good arguments why its reagents did not literally infringe the '704 patent. It also had many good reasons to believe the doctrine of equivalents would be similarly unavailing to Innogenetics.

First, the doctrine was not available to Innogenetics in this case because its application would vitiate Innogenetics' own claim language. Infringement under the doctrine of equivalents may occur when an accused product or process differs from the claimed invention only insubstantially. *ACCO Brands, Inc. v. Micro Sec. Devices, Inc.*, 346 F.3d 1075, 1080 (Fed. Cir. 2003); *Boehringer Ingelheim Vetmedia, Inc. v. Schering-Plough Corp.*, 320 F.3d 1339, 1351 (Fed. Cir. 2003). But under well-settled Federal Circuit and Supreme Court precedent, the doctrine of equivalents may not be applied to allow coverage over matter that was excluded by the actual claim language; that is, it cannot be used to vitiate or do away with claim limitations that the patentee inserted into its own patent. *Warner-Jenkinson Co., Inc. v. Hilton Davis Chemical Co.*, 520 U.S. 17, 29 (1997); *see also Bell Atl. Network Servs., Inc. v. Covad Comm'n Group, Inc.*, 262 F.3d 1258, 1279-80 (Fed. Cir. 2001).

Here, establishing infringement under the doctrine of equivalents would mean stretching the claim element "detecting a complex as formed with said probe and said nucleic acids of HCV" to include not detecting a complex and instead detecting fluorescence in solution, which occurs only as a result of the formation and subsequent enzymatic destruction of a probe-target complex in realtime PCR reaction.[85] This breadth would vitiate the claim limitations (1) "complex as formed," (2) "with said probe" and (3) "said nucleic acids of HCV."

[85] *See* Opinion and Order, 8/11/08, Dkt. No. 218, at 9-10.

Accordingly, the doctrine cannot be applied as broadly as a judgment of equivalent infringement would require in this case.

Also, the doctrine may not be applied in situations where, as here, it would extend coverage of a claim element to matter that is the opposite, or antithesis, of that claim element. Instead of detecting a complex as formed, as the claims require, the use of Abbott's reagents involves destroying a complex as formed prior to detecting anything, and what is detected therefore cannot be the complex or any equivalent thereof.[86] The law is clear that under such circumstances, application of the doctrine of equivalents is barred. *See Moore U.S.A. Inc. v. Standard Register Co.*, 229 F.3d 1091 (Fed. Cir. 2000) (affirming summary judgment of nonequivalence where the claims required adhesive along "a majority of the lengths," and the accused product had adhesive along only 48% of the lengths, because "it would defy logic to conclude that a minority – the very antithesis of a majority – could be insubstantially different from a claim limitation requiring a majority").

Finally, the claim language in question was the result of a substantial narrowing by the applicant during the prosecution of the patent, and Innogenetics is estopped from now trying to recapture the lost claim scope. The originally filed claim language was "detecting the complexes possibly formed between said probe and the nucleotide sequence of the HCV isolate to be identified."[87] Here, application of the doctrine would go far beyond this disclaimed claim scope to capture claim scope never even suggested by the inventors, which is impermissible. *See*

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[86] Abbott's Proposed Findings of Fact ("PFOF"), 5/15/06, Dkt. No. 52, ¶¶ 36-37, 39, 67-70 Rossau Depo, 3/24/06, Dkt. No. 85, 151:12-21; 152:2-9; First Reznikoff Report, 4/21/06, Dkt. No. 38, p. 10, 18; Patterson Non-Infringement Expert Report, Dkt. No. 39, pp. 6-8; Deposition of William Reznikoff, 4/27/05, Dkt. No. 92, 97:25-98:13.

[87] Abbott PFOF, Dkt. No. 52, ¶ 59; DX 301, '704 file wrapper at 00070, Gross Decl., Ex J.

Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co. Ltd.,535 U.S. 722, 733-34 (2002); *see also Loctite Corp. v. Ultraseal Ltd.*,781 F.2d 861, 870 (Fed. Cir. 1985) (rev'd on other grounds).

Further, even if the doctrine of equivalents were available under law, and it is not, there was definitely doubt as to whether Innogenetics would be able to satisfy the required "insubstantial difference test" or "function-way-result test" that must accompany any doctrine of equivalents analysis. *See, e.g., Dawn Equip. Co. v. Kentucky Farms, Inc.*, 140 F.3d 1009, 1016 (Fed. Cir. 1998). To prevail under this doctrine, "a patentee must … provide particularized testimony and linking argument as to the 'insubstantiality of the differences' between the claimed invention and the accused device or process, or with respect to the function, way, result test …." *Network Commerce, Inc. v. Microsoft Corp.*, 422 F.3d 1353, 1363 (Fed. Cir. 2005) (*citing Texas Inst., Inc. v. Cypress Semiconductor Corp.*, 90 F.3d 1558, 1567 (Fed. Cir. 1996)). The record is devoid of any doctrine of equivalents analysis by Innogenetics or the Court.[88]

It is perhaps instructive that at summary judgment, Innogenetics only cursorily stated, with no elaboration, that the "detecting a complex" element is satisfied "by a method that has the same function, practiced in substantially the same way, to accomplish the same result as that disclosed in the '704 patent."[89] Innogenetics did not address the substance of the differences between the claimed method and Abbott's technology, nor did it address any of the evidence that Abbott's accused reagents (1) perform a different function (*i.e.*, emission of fluorescent light in solution)[90] and (2) work in a different way (*i.e.*, through exonuclease digestion of probe

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[88] Opinion and Order, 8/11/06, Dkt. No. 218, at 24 ("It is unnecessary to discern infringement under the doctrine of equivalents at this stage in the proceedings").

[89] Innogenetics' Responsive Proposed Findings of Facts, 6/6/06, Dkt. No. 74, Fact. No. 88 (emphasis added).

[90] *See* Opinion and Order, 8/11/08, Dkt. No. 218, at 9.

complexes and cleavage of fluorescent dye molecules),[91] and (3) achieve a different result (*i.e.*, optical detection of progressively intensifying fluorescence, id. at 9-10) than the claimed method. *Network Commerce*, 422 F.3d at 1363 (noting that even "[g]eneralized testimony as to the overall similarity between the claims and the accused infringer's product or process will not suffice.").

Moreover, infringement under the doctrine of equivalents is a question of fact to be decided by the jury. *See, e.g., Cook Biotech Inc., v. Acell, Inc.*, 460 F.3d 1365, 1372 (Fed. Cir. 2006) ("Infringement, whether literal or under the doctrine of equivalents, is a question of fact."). Had the doctrine been available, and the issue gone to the jury, Abbott stood ready to present extensive evidence on the significant and numerous differences between the function, way, and results achieved through realtime PCR using TaqMan probes and the conventional methods of "detecting a complex that is or has been formed" known in the field in 1992.[92]

C. Abbott Had Good Reason To Request, and To Expect, The Claim Construction It Proposed For "Detecting a Complex As Formed With Said Probe and Said Nucleic Acids Of HCV"

In this case, the parties proposed two competing constructions of the claim element "detecting a complex as formed with said probe and said nucleic acids of HCV":

> **Abbott**: Detecting a complex that is formed with said probe and said nucleic acids of HCV.
>
> **Innogenetics**: Any process by which one can determine that a hybridization complex has been formed between the probe and nucleic acids of HCV.[93]

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[91] *Id.*

[92] Patterson Non-Infringement Expert Report, 5/2/06, Dkt. No. 39, at 15-17.

[93] *See* Abbott Laboratories' Proposed Findings of Fact, 5/15/06, Dkt. No. 52, ¶ 50.

The facts clearly favored Abbott's interpretation of this claim term, as is suggested by even a glance at the proposed constructions. First, Abbott's proposed claim construction closely mirrored the claim language itself, which is supposed to be the starting point for any claim construction analysis. *See Phillips v. AWH Corp.*, 415 F.3d 1303, 1312 (Fed. Cir. 2005) (en banc). The claim language specifies "detecting a complex," not the detection of a free-floating molecule that was once attached to a probe that was once part of a complex; in other words, it expressly requires that a complex be detected, not a remnant of the complex after it is destroyed. The next limitation, "as formed," reinforces this point by requiring that the complex detected not be an artifact of the destruction of a previously-formed complex, but must be a "complex as formed." As any English dictionary will explain,[94] the word "as," when used in a phrase like "detecting a complex as formed," means "at the time that" and reflects the present tense. And the claim itself even specifies the makeup of the complex to be detected: it must be a complex "as formed with said probe and said nucleic acids of HCV."[95]

The specification also solidly supported Abbott's proposed construction and its view that the claim required detection of a complex in existence at the time of detection. Uniformly, the specification discloses the invention in terms of using a solid substrate (such as

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[94] **as…**--conj. … 3. At the same time that: WHILE. *Webster's II New Riverside University Dictionary* (1984), p. 128.

as…--conj. … 3. At the same time that: WHILE. *The American Heritage Dictionary* (Second College Edition, 191), p. 131.

as…--CONJUNCTION. … 3. At the same time that: WHILE. *The American Heritage Dictionary of the English Language* (4th ed. 2000), http://www.bartleby.com/61/1/A0450100.html.

As 1. *conj* **at the time that:** used to indicate that something happens at the same time as something else. *Encarta World English Dictionary* (2006), http://encarta.msn.com/encnet/features/dictionary/DictionaryResults.aspx?refid=1861587033.

[95] DX 300, '704 patent; Gross Decl., Ex. K.

the LiPA strip) for detecting actual complexes between probe and target.[96] Also, whenever the specification describes the "detection" event, it is consistently in terms of a hybrid, or complex, or hybridization complex, or the like.[97] Every figure depicting a physical embodiment of the invention displays an observable pattern created by the hybridization products formed between probes and targets.[98]

The narrowing of the claim language by the applicant that took place during the prosecution also steers sharply toward Abbott's proposed construction. The applicants' original claim language started with "detecting the complexes possibly formed between said probe and the nucleotide sequence of the HCV isolate to be identified,"[99] was amended to "detecting any complex as formed with said probe and nucleotide sequence of the HCV isolate to be identified,"[100] and then amended again to the final language: "detecting a complex as formed with said probe and said nucleic acids of HCV."[101] These amendments show that the applicants focused their claim choice to specify detecting an actual complex as formed with a probe and nucleic acids of HCV.

Abbott's proposed claim construction was also informed by the expert opinion of Dr. Patterson, whose reports explained the state of the art at the relevant time and suggested a

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[96] *Id.*, 4:41-49.

[97] *Id.*, 6:64-67; 10:5-26; 20:16-28; 20:41-42; 21:5-6.

[98] *Id.*, Figures 3, 6-10; 21:33-52; 22:12-54.

[99] DX 301, Gross Decl., Ex. J, '704 File Wrapper at 00070.

[100] *Id.*, '704 File Wrapper at 00749.

[101] *Id.*, '704 File Wrapper at 00799.

claim construction that he felt most accurately reflects the meaning of the claim language to one of ordinary skill in the art at the time of the invention claimed in the '704 patent.[102]

The Court did not construe the entire claim element, and instead focused only on the words "detecting a complex as formed" and interpreted them to mean "detecting a complex that is or has been formed."[103] The Court did not consider or construe the important limitations "with said probe and said nucleic acids of HCV," the language that identifies the precise composition of the complex that is detected during this step of the claimed method. The Court's construction did not reflect the complete claim language, or the precision with which Innogenetics claimed the nucleic acid complex that is detected; it was legally flawed and was an improper basis for the entry of judgment as a matter of law on infringement. *Callicrate v. Wadsworth Mfg., Inc.*, 427 F.3d 1361, 1369 (Fed. Cir. 2005) (finding error in district court's claim construction for failing to reflect the actual claim language) (citing *Playtex Prod., Inc. v. Procter & Gamble Co.*, 400 F.3d 901, 909-10 (Fed. Cir. 2005), for the proposition that a claim construction is flawed if it ignores claim language.) That the Court chose an improper construction does not make Abbott culpable – or punishable – for supporting a proper one.

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[102] Patterson Non-Infringement Expert Report, at 2-4; *see also* Expert Report of Bruce K. Patterson, M.D. Regarding The Invalidity of Innogenetics, N.V.'s U.S. Patent No. 5,846,704, 4/10/06 ("Patterson Invalidity Expert Report"), Dkt. No. 33, at 2-13.

[103] Opinion and Order, 8/11/06, Dkt. 218, at 31.

D. It Was Not Apparent to Abbott, Or To Anyone Else, Court and Innogenetics Included, that Abbott's Non-Infringement Defenses Had Been Precluded Until the Moment the Court Granted Judgment As a Matter of Law Against It

Innogenetics' brief relies heavily on the proposition that Abbott is culpable for not recognizing the failure of its noninfringement defense before the first day of trial, August 28, 2006. The problem with this, of course, is that Abbott's defense had not failed.

As detailed above, the facts on infringement that had been developed throughout the course of the litigation were in Abbott's favor. So much so, in fact, that Abbott brought a motion for summary judgment on the issue, and Innogenetics did not. And although Abbott's motion was filed on May 15, it was not until August 11, just a few weeks before trial, that the Court issued its ruling denying the motion.

The Court's order did not suggest that it was granting judgment in favor of Innogenetics or that the question of infringement was anything other than a question for the jury. With respect to claim 1, the Court merely noted its view that Abbott had not proven "the absence of any material dispute,"[104] and that Innogenetics had "adduced sufficient evidence to go to the jury." [105] Although the Court noted that it seemed "likely" that based on its claim construction, Abbott's products would be found to infringe,[106] it later recognized that the infringement determination was for the jury and agreed to exclude the infringement-related findings and comments in its order from the jury's view: ". . . as to the opinion, of course they can't put in anything except the claim construction."[107]

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[104] *Id.*, at 24.

[105] *Id.*, at 24.

[106] *Id.*, at 23.

[107] Trial Tr., 8/28/06, v. I, 5:17-20; 6:5-8. Innogenetics did not oppose.

Moreover, the Court purposefully did not enter judgment against Abbott[108] and the Court and both parties all contemplated that the issue would go to the jury. Six days after the Court's order denying Abbott's motion for summary judgment, on August 17, 2006, the Court's "plan" was to "try both infringement and validity together"[109] and counsel and the Court discussed how much time would be needed to try the infringement case.[110] Eleven days after that, on August 28, 2006, Innogenetics was asked to clarify which claims were being asserted as infringed.[111] Then the Court gave preliminary instructions on infringement,[112] and Innogenetics' counsel gave its opening statement including infringement[113] and at no time did Innogenetics' counsel ever object that all this activity was superfluous because judgment had already been granted against Abbott on infringement. It was not until later, after the jury was excused, that Innogenetics began rearguing the Court's August 11 order in an attempt to move for judgment as a matter of law against Abbott.[114] When Abbott's counsel pointed out that the Court had reserved the issue for the jury, the Court called this a "misapprehension"[115] and notified Abbott for the first time that infringement "is not an issue for the jury" and that it would not be allowed

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[108] Opinion and Order, 8/11/06, Dkt. 218, at 24; Trial Tr., 8/28/06, v. I, 68:3-7 (Abbott's counsel: ". . . if the Court believed that there was not a triable issue of fact, Abbott submits the Court could have entered summary judgment on infringement against Abbott." The Court: "It entered my mind").

[109] Pretrial Conf. Tr., 8/17/06, Dkt. No. 260, 3:14-19.

[110] Pretrial Conf. Tr., 8/17/06, Dkt. No. 260, 3:20-4:6.

[111] Trial Tr. 8/28/06, v. I, 13:4-14:24.

[112] Trial Tr. 8/28/06, v. I, 17:25-19:14; 23:1-10; 24:22-25:4.

[113] Trial Tr. 8/28/06, v. I, 50:11-18; 51:1-25.

[114] Trial Tr. 8/28/06, v. I, 60:6-62:6; 65:1-10.

[115] Trial Tr. 8/28/06, v. I, 68:12-69:25 (The Court: "Let me just cure any misapprehension you may be labeling [sic] under. That is not an issue for the jury. . . . It was a misapprehension. That is not what you're going to be allowed to do").

to present a noninfringement case. At this point, Innogenetics moved for judgment as a matter of law, which was summarily granted.[116]

So the suggestion now by Innogenetics that it "was apparent [after the Court's claim construction] that Abbott had no infringement defense"[117] is demonstrably false. As is the suggestion that Abbott somehow "increas[ed] the administrative burden on the Court and the litigation costs that had to be borne by Innogenetics."[118] Clearly, it was not obvious to anyone that Abbott had no noninfringement case to present to the jury (until the entry of JMOL).[119]

IV. THE FACTS OMITTED FROM INNOGENETICS' BRIEF SHOW ABBOTT IN FACT HAD A STRONG INVALIDITY CASE ON BOTH ANTICIPATION AND OBVIOUSNESS AND WAS RIGHT IN PURSUING EACH OF THESE DEFENSES

Innogenetics argues that Abbott should be punished with enhancement and an attorneys' fees award for pursuing "clearly unmeritorious" invalidity defenses. But Innogenetics measures these defenses not on their actual merits – indeed, there is almost no mention in its brief of the merits of any of the references involved – but on their ultimate disposal, which in every case was caused directly or indirectly by the Court's improper rulings. That is because

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[116] Trial Tr. 8/28/06, v. I, 73:1-74:7. Innogenetics quotes a statement by Abbott's counsel that Abbott was "defenseless" to falsely suggest that Abbott believed it had no defense at all. When read in its proper context, it is clear that counsel was referring to the fact that the Court had just decided the issue of infringement against it. Trial Tr. 8/28/06, v. I, 68:19-75:16.

[117] Motion, at 2.

[118] Motion, at 2. Also, it bears noting that Innogenetics has not presented any supporting evidence of these greatly increased costs and burdens.

[119] Motion, at 24. Innogenetics' contention that Abbott "drop[ped]" its infringement defense is also fictitious. Abbott fought for its right to present noninfringement to the jury right up until the Court entered JMOL against it. (Trial Tr. 8/28/06, v. I, 72:24-74:7).

when these references are considered on their merits, it is clear that Abbott had more than a good faith basis to assert them through trial.

A. The Cha PCT Reference Anticipated And Rendered Obvious The Claims Of The '704 Patent

1. Evidence Presented By Dr. Patterson At Trial Established That The Disclosures of the Cha PCT Application Contain All of The Elements Of The Claims Of The '704 Patent

With its usual hyperbolic inaccuracy, Innogenetics broadly proclaims that "the evidence of anticipation presented by Abbott was totally insufficient – and, in addition, wholly lacking on the issue of enablement."[120] In fact, however, despite the Court's improper decision to prevent Dr. Cha, the inventor of the Cha prior art reference, from doing anything other than introducing himself and reading from the Cha PCT's disclosure, and the Court's other improper decision to exclude evidence of the Cha '693 patent, whose identical disclosure to the PCT application enjoys a presumption of enablement, Abbott presented sufficient evidence at trial that the Cha PCT Application anticipated and enabled claims 1-8, 12 and 13 of the '704 patent, as construed by the Court.

The Cha PCT Application, published on November 12, 1992 and thus predating Innogenetics' application by one year and two weeks, is prior art under Section 102(a) because its publication pre-dates Innogenetics' invention,[121] and under Section 102(b) because its publication pre-dates Innogenetics' critical date.[122]

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[120] Motion, at 13.

[121] For purposes of Section 102(b), the "critical date" – i.e., the date "more than one year prior to the date of invention" is November 26, 1992, a year before Innogenetics' filing of its PCT application. *See Pfaff v. Wells Elecs.*, 124 F.3d 1429, 1433 (Fed. Cir. 1997). Because the (footnote continued)

The Cha PCT Application describes a method of genotyping the hepatitis C virus as well as methods of peptide and antibody conjugations for serologic assays.[123] The Cha PCT describes a sandwich assay, which is a method that uses two probes instead of one probe to detect a particular target sequence.[124] The sandwich assay described incorporates probes falling within the 5' UT (untranslated) region of the hepatitis C virus.[125] Sandwich assays can be used to genotype by using genotype-specific capture probes and a common detection probe.[126] The Cha PCT Application discloses the location of the nucleotide sequences in the 5' UT region[127] and indicates which probes of the sandwich assay are aligned with the 5' UT region of hepatitis C.[128]

Cha PCT Application was "described in a printed publication" before the critical date, it qualifies as prior art under Section 102(b). Section 102(a) pertains to date of invention, entitling an applicant to a patent unless: (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant . . . . 35 U.S.C. section 102(a).

[122] The date of Innogenetics' "invention" of the '704 patent, statutorily, can be no earlier than November 27, 1992, the filing date of its related European application (reflected on the first page of the '704 patent). When Innogenetics applied for its U.S. patent, applicants were forbidden from relying on their activities outside of the United States to establish an earlier date of invention, with certain exceptions. *See* 35 U.S.C. sections 104, 119, 365 (1992); *see also* Pub. L. 103-182. These statutory exceptions, which remain part of the current law, allow foreign applicants to take advantage of their foreign filing dates to establish dates of invention earlier than their U.S. filing dates. In other words, the '704 patent, which is a U.S. "national stage" application of a PCT application, may be entitled to a date of invention of November 27, 1992, the filing date of Innogenetics' European application, assuming it described the same invention as the '704 patent. Even with a priority date of November 27, 1992, however, Innogenetics' invention came *after* the November 12, 1992 publication of the Cha PCT application, which is prior art under Section 102(a).

[123] Trial Tr., 8/29/06, v. II, 43:23-44:2.

[124] Trial Tr., 8/29/06, v. II, 44:6-11.

[125] Trial Tr., 8/29/06, v. II, 44:20-24.

[126] Trial Tr., 8/29/06, v. II, 45:4-7.

[127] Trial Tr., 8/29/06, v. II, 47:17-48:2.

[128] Trial Tr., 8/29/06, v. II, 47:22-48:2.

The Cha PCT Application also describes other probe-based methods of genotyping, including a method involving a polymerase chain reaction ("PCR") followed by detection with genotype-specific probes in order to provide the genotype analysis.[129] The probes bind to target sequences within the 5' UT region.[130] In particular, probes 77 and 78 as listed in the Cha PCT Application bind within the region of minus 291 to minus 66.[131]

The Cha PCT Application teaches a method of detecting the complex formed between probes and these genotype-specific sequences.[132] It involves a method of converting the hepatitis RNA into what is called a cDNA or complimentary DNA.[133] That DNA is then amplified by the PCR, which makes it easier to detect by making millions of copies of the DNA.[134] After the PCR is done on an isolate of hepatitis C from a biological sample, the genotyping is done using probes 77 and 78.[135] Someone of ordinary skill in the art in 1992 would have understood from the Cha PCT Application how to distinguish and classify types of HCV using this probe-based method.[136]

Claim 1

Claim 1 of the '704 patent recites "A method of genotyping HCV present in a biological sample comprising hybridizing nucleic acids in a biological sample with at least one probe and detecting a complex as formed with said probe and said nucleic acids of HCV using a

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[129] Trial Tr., 8/29/06, v. II, 49:13-19.

[130] Trial Tr., 8/29/06, v. II, 49:20-24.

[131] Trial Tr., 8/29/06, v. II, 50:1-6.

[132] Trial Tr., 8/29/06, v. II, 50:12-15.

[133] Trial Tr., 8/29/06, v. II, 50:17-19.

[134] Trial Tr., 8/29/06, v. II, 50:19-23.

[135] Trial Tr., 8/29/06, v. II, 50:24-51:1.

probe that specifically hybridizes to the domain extending from the nucleotides of positions -291 to -66 of the 5' untranslated region of the HCV," the hepatitis C virus.[137] The Court construed "detecting a complex as formed" as "detecting a complex that is or has been formed.[138] The Court construed "method of genotyping" as a "method that distinguishes among types and/or subtypes of hepatitis C virus (HCV) and classifies the HCV into a genotype or subtype."[139] The Court construed "specifically hybridizing" as "hybridizing to a target sequence and not to a non-target sequence."[140] Thus, claim 1 as construed by the Court, requires (1) genotyping hepatitis C present in a biological sample, (2) detecting a complex as formed, and (3) specifically hybridizing a probe to a domain extending from minus 291 to minus 66 of the 5' UTR region of hepatitis C.[141]

(a) Genotyping Hepatitis C Present In A Biological Sample

In the Cha PCT Application, the inventor states that the present invention features compositions of matter comprising nucleic acids and peptides corresponding to the HCV viral genome which define different genotypes, and that the present invention also features methods of using the compositions corresponding to sequences of the HCV viral genome which define different genotypes described herein.[142]

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[136] Trial Tr., 8/29/06, v. II, 51:2-6.

[137] DX 300, '704 patent, Gross Decl., Ex. K, 113:1-7.

[138] Opinion and Order, 8/11/06, Dkt. 218, at 31.

[139] *Id.*, at 31.

[140] *Id.*, at 22, 31.

[141] Trial Tr., 8/29/06, v. II, 52:19-23. *See also* Defendant Abbott Laboratories' Brief In Support of Its Motion For Summary Judgment, 5/15/06, Dkt. No. 51, incorporated by reference herein, at 34-37, for more discussion of how the Cha PCT Application anticipates Claim 1 of the '704 patent.

[142] DX 303, Cha PCT Application, 7:20-26; Gross Decl., Ex. D.

On page 9 of the Cha PCT Application, it explains that hepatitis C has at least five genotypes which will be referred to in the Application by the designations GI through GV.[143] The first genotype, (GI), is exemplified by sequences numbered 1-6, 23-25, 33-38 and 52-57.[144] The second genotype, (GII), is exemplified by sequences numbered 7-12, 26-28, 39-45 and 58-64.[145] The third genotype, (GIII), is exemplified by sequences numbered 13-47, 32, 46-47 and 65-66.[146] Sequences numbered 38 through 51 are the genotype-specific regions in the 5' UT.[147]

The 33 through 51 sequences contain these genotype specific sequences.[148] The first 5' UT genotype is exemplified by the sequences within sequences numbered 33 through 38. A second 5' UT genotype is defined by the sequences within sequences numbered 39-45. A third 5' UT genotype is exemplified by the sequences within sequences numbered 46 and 47. A fourth 5' genotype is exemplified by sequences within sequences numbered 48 and 49. And a fifth 5' UT genotype is exemplified by sequences within sequences numbered 50 and 51.[149]

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[143] Trial Tr., 8/29/06, v. II, 53:10-13; DX 303, Cha PCT Application, Gross Decl., Ex. D, 9:20-22.

[144] Trial Tr., 8/29/06, v. II, 53:14-15; DX 303, Cha PCT Application, Gross Decl., Ex. D, 9:22-23.

[145] Trial Tr., 8/29/06, v. II, 53:15-17; DX 303, Cha PCT Application, Gross Decl., Ex. D, 9:23-25.

[146] Trial Tr., 8/29/06, v. II, 53:17-18; DX 303, Cha PCT Application, 9:25-27.

[147] Trial Tr., 8/29/06, v. II, 53:18-20.

[148] Trial Tr., 8/29/06, v. II, 55:18-21; DX 303, Cha PCT Application, Gross Decl., Ex. D, 20:19-26.

[149] Trial Tr., 8/29/06, v. II, 55:10-18; DX 303, Cha PCT Application, Gross Decl., Ex. D, 21:1-9.

Table 1 of the Cha PCT Application lists the sequences of primers and probes.[150] Primers are used in the PCR reaction.[151] Once the copies of the relevant DNA are made, the probes are used to genotype those particular regions.[152] The nucleotide position identified in Table 1 indicates not only where those primers and probes reside in relation to the hepatitis C genome, but also in relation to one another.[153]

The Cha PCT Application clearly explains that for the cDNA synthesis and PCR amplification part of the method, a protocol developed by Perkin-Elmer/Cetus (GeneAmp RNA PCR kit), a common commercially available kit, was used in the experiments.[154] Such kits come with directions on how to use the particular reagents.[155]

The Cha PCT Application states that the purpose of the tests and assays is to genotype,[156] meaning that one of ordinary skill in the art in 1992 would be able to distinguish and classify using that technology, those particular genotypes, in particular genotype III and genotype IV.[157]

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[150] Trial Tr., 8/29/06, v. II, 56:2-4; DX 303, Cha PCT Application, Gross Decl., Ex. D, 36:11-27 (Table 1).

[151] Trial Tr., 8/29/06, v. II, 56:4; DX 303, Cha PCT Application, Gross Decl., Ex. D, 23:15-24:6.

[152] Trial Tr., 8/29/06, v. II, 56:4-7; DX 303, Cha PCT Application, Gross Decl., Ex. D, 22:10-27.

[153] Trial Tr., 8/29/06, v. II, 56:7-11; DX 303, Cha PCT Application, Gross Decl., Ex. D, 36:11-27 (Table 1).

[154] Trial Tr., 8/29/06, v. II, 56:13-22; DX 303, Cha PCT Application, Gross Decl., Ex. D, 37:1-15.

[155] Trial Tr., 8/29/06, v. II, 57:2-5.

[156] Trial Tr., 8/29/06, v. II, 57:7-9; DX 303, Cha PCT Application, Gross Decl., Ex. D, 37:16-17.

[157] Trial Tr., 8/29/06, v. II, 60:22-61:4.

In one experiment disclosed, the PCR products were generated with sequences 79 and 80.[158] These primers are short pieces of DNA that form the basis by which a particular enzyme amplifies the sequence in between the two primers.[159] So the primers amplify the region so the DNA can be detected more easily.[160] Then the probes are used to detect the PCR products in a genotype-specific way.[161]

(b) Detecting A Complex As Formed

This part of the claim deals with the connection between making the complex to arriving at a diagnosis of a particular genotype.[162] Both the '704 patent and the Cha PCT Application use dye radioactive detection, which involves using a synthetic nucleic acid as a probe, with some sort of dye or radioactive "label" molecule on that particular probe that allows it to be detected either visually or certainly with a variety of different instruments if it has formed a probe complex.[163] If the probe doesn't find its exact target, it is washed away and would not be detectable.[164]

(c) Specifically Hybridizing A Probe To A Domain Extending From Minus 291 To Minus 66 Of The 5' UT Region of Hepatitis C

The Cha PCT Application discloses a method of detecting a complex as formed of said probe and said nucleic acid of HCV, which is evident by the reaction in the experiment

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[158] Trial Tr., 8/29/06, v. II, 57:11-13; DX 303, Cha PCT Application, Gross Decl., Ex. D, 38:8-15.

[159] Trial Tr., 8/29/06, v. II, 57:13-17.

[160] Trial Tr., 8/29/06, v. II, 57:13-16.

[161] Trial Tr., 8/29/06, v. II, 57:17-18; DX 303, Cha PCT Application, Gross Decl., Ex. D, 38:8-15.

[162] Trial Tr., 8/29/06, v. II, 60:2-5.

[163] Trial Tr., 8/29/06, v. II, 54:6-55:2; 60:5-11.

described in the Application about binding the Probe 77 and 78 to sequences corresponding to genotype III and genotype IV of hepatitis C.[165] In Table 1, the nucleotide positions are listed for sequence numbers 79 and 80 in the 5' UTR region as being within the negative 291 to negative 266 domain.[166] In the experiment, sequence number (or probe) 77 bound to the 5' UT of genotype III and sequence number (or probe) 78 bound to the 5' UT of genotype IV.[167] The Cha PCT Application explains in this experiment how probes 77 and 78 specifically hybridize.[168] It says that "Each sequence hybridized in a genotype-specific manner," which means that it only bound to a virus of the genotype of interest and did not bind to other genotypes.[169] A person of ordinary skill in the art in 1992 would have understood that this sentence meant that there was specific hybridization.[170]

Claim 2

Claim 2 is "The method of claim 1 wherein a set of at least two different hybridization probes is used simultaneously."[171]

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[164] Trial Tr., 8/29/06, v. II, 60:9-11.

[165] Trial Tr., 8/29/06, v. II, 60:12-20.

[166] Trial Tr., 8/29/06, v. II, 57:20-58:3; 58:10-15; DX 303, Cha PCT Application, Gross Decl., Ex. D, 36:11-27 (Table 1).

[167] Trial Tr., 8/29/06, v. II, 58:17-24; 59:11-15.

[168] Trial Tr., 8/29/06, v. II, 59:16-18; DX 303, Cha PCT Application, Gross Decl., Ex. D, 38:14-15.

[169] Trial Tr., 8/29/06, v. II, 59:16-21; DX 303, Cha PCT Application, Gross Decl., Ex. D, 38:14-15.

[170] Trial Tr., 8/29/06, v. II, 59:22-25.

[171] DX 300, '704 patent, Gross Decl., Ex. K, 113:7-8.

At least one example of this is found in the Cha PCT Application: "The formation of a hybridization product has utility as a means of separating one or more genotypes of HCV nucleic acid from other constituents potentially present."[172]

The Cha PCT Application further discloses: "Nucleic acid 'sandwich assays' employ one nucleic acid associated with a label and a second nucleic acid associated with a support. An embodiment of the present invention features a sandwich assay comprising two nucleic acids, both have sequences which correspond to HCV nucleic acids, however, at least one non-naturally occurring nucleic acid has a sequence corresponding to a non-HCV-1 HCV nucleic acid."[173] The support described is a paper, nylon, or nitrocellulose, which nucleic acids stick to.[174] A capture probe, which lies within the 5' UT, is used to bind to the 5' UT of hepatitis C and adhere the viral nucleic acids to the piece of paper.[175] To detect whether or not the virus nucleic acids are bound to the piece of paper, a detection probe is used.[176] The detection probe also has a region that binds to the 5' UT, but also has a complementary region that binds [to a] structure that looks like a Christmas tree.[177] The "Christmas tree" structure is called an amplifier and the "branches" of the "tree" are stretches of nucleic acids.[178] At the end of those nucleic acids, probes bind that carry the label, which produces light in the form of

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[172] Trial Tr., 8/29/06, v. III, 8:7-11; DX 303, Gross Decl., Ex. D, Cha PCT Application, 11:10-13.

[173] Trial Tr., 8/29/06, v. III, 8:13-20; DX 303, Gross Decl., Ex. D, Cha PCT Application, 11:17-24.

[174] Trial Tr., 8/29/06, v. III, 8:22-25.

[175] Trial Tr., 8/29/06, v. III, 9:1-5.

[176] Trial Tr., 8/29/06, v. III, 9:5-8.

[177] Trial Tr., 8/29/06, v. III, 9:7-10.

[178] Trial Tr., 8/29/06, v. III, 9:10-12.

"chemiluminescence."[179] Instruments are then used to detect light, radioactivity, fluorescent dyes, to determine what has been bound to the piece of paper.[180] A person of ordinary skill in the art in 1992 would have understood from reading the Cha PCT Application that Cha was practicing the method of Claim 2 of the '704 patent.[181]

Also, the Cha PCT Application states: "A nucleic acid isolated or synthesized in accordance with a sequence defining a particular genotype of a region of the HCV genome can be used as a probe to detect such genotype or used in combination with other nucleic acid probes to detect substantially all general types of HCV."[182]

In addition to the sandwich assay previously described, the Cha PCT Application teaches how to perform a HCV genotyping assay using PCR.[183] The Application teaches a specific protocol to be used, including PCR cycling times and temperatures.[184] The Cha PCT Application also lists specific primers Sequence IDs 79 and 80 that can be used to amplify the 5' UT.[185] Subsequent to this amplification, HCV is genotyped using genotype-specific probes (Sequence IDs 77 and 78) that specifically hybridize to the amplified product.[186] The Cha PCT Application teaches that the amplification product can be transferred to a solid support and then

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[179] Trial Tr., 8/29/06, v. III, 9:12-15.

[180] Trial Tr., 8/29/06, v. III, 9:16-18.

[181] Trial Tr., 8/29/06, v. III, 9:19-22.

[182] Trial Tr., 8/29/06, v. III, 10:8-12; DX 303, Cha PCT Application, Gross Decl., Ex. D, 22:10-16 (emphasis added).

[183] Trial Tr., 8/29/06, v. III, 11:12-14.

[184] Trial Tr., 8/29/06, v. III, 11:15-16.

[185] Trial Tr., 8/29/06, v. III, 11:16-18.

[186] Trial Tr., 8/29/06, v. III, 11:19-21.

hybridized with genotype-specific probes to perform a HCV genotyping assay.[187] The Cha PCT Application teaches that Sequence ID 77 identifies Genotype III of HCV and Sequence ID 78 identifies Genotype IV of HCV.[188] It states, "each sequence hybridized in a genotype-specific manner."[189]

Claim 3

Claim 3 requires "the method of Claim 1, wherein the HCV domain comprises, at least five contiguous nucleotides in a domain selected from the group consisting of" a list of elements, (a) through (j).[190] Sequence 78 of the Cha PCT Application (identified as sequence 13 in the '704 patent, covers the entire domain (position -170 to -155) in Section (f) of Claim 3.[191] A person of ordinary skill in the art in 1992 would have understood from reading the Cha PCT Application that Cha was practicing the method of Claim 3 of the '704 patent.[192]

Claim 4

Claim 4 requires "The method of claim 1 wherein a set of at least two different probes for each type or subtype of HCV to be determined is used, wherein each probe set

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[187] Trial Tr., 8/29/06, v. III, 11:21-25.

[188] Trial Tr., 8/29/06, v. III, 11:26-12:2; DX 303, Cha PCT Application, Gross Decl., Ex. D, 38:8-15.

[189] Trial Tr., 8/29/06, v. III, 12:2-3. *See also* Defendant Abbott Laboratories' Brief In Support of Its Motion For Summary Judgment, 5/15/06, Dkt. No. 51, incorporated by reference herein, at 37-38, for more discussion of how the Cha PCT Application anticipates Claim 2 of the '704 patent.

[190] DX 300, '704 patent, Gross Decl., Ex. K, 113:9-32; Trial Tr., 8/29/06, v. III, 11-14.

[191] Trial Tr., 8/29/06, v. II, 17:22-18:3; v. III, 12:24-13:1; DX 303, Cha PCT Application, Gross Decl., Ex. D, 36:12-27.

[192] Trial Tr., 8/29/06, v. III, 13:4-8. *See also* Defendant Abbott Laboratories' Brief In Support of Its Motion For Summary Judgment, 5/15/06, Dkt. No. 51, incorporated by reference herein, at 38-39, for more discussion of how the Cha PCT Application anticipates Claim 3 of the '704 patent.

hybridizes to a pair of domains selected from the group of domain pairs consisting of" several Markush elements.[193] "The Cha PCT Sequence ID 78, 123 and 126E encompass entirely several of the probe pairs described in Claim 4.[194] For Sequence ID 78 and 123, each encompasses entirely the domain extending between nucleotides at positions -170 and -155, and Sequence ID 126E encompasses entirely the domain extending between the nucleotides at positions -83 to -68.[195] As described in the fifth paragraph of Claim 4, Cha taught and disclosed the use of Sequence IDs 78, 123, and 126E for genotyping hepatitis C.[196] The Cha PCT Application went beyond just disclosing a domain pair, like Claim 4 requires, and actually disclosed three genotype-specific domains.[197]

Claim 5

Claim 5 recites: "The method of Claim 1 wherein the HCV to be genotyped is selected from the group consisting of HCV Type 1, Type 2, Type 3, Type 4, Type 5 and Type 6."[198]

Genotypes one, two, three, four and five in the Cha PCT Application correspond to genotypes 1, 1b, 2a, 3a, and 4 in the 704 Patent, respectively.[199] Specifically, probes 77 and 78 genotype hepatitis C, genotype III, which in the '704 application is 2a, and genotype IV,

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193 DX 300, '704 patent, Gross Decl., Ex. K, 113:9-32;

194 Trial Tr., 8/29/06, vol. III, 19:1-3.

195 Trial Tr., 8/29/06, vol. III, 19:6-10.

196 Trial Tr., 8/29/06, vol. III, 19:11-13.

197 Trial Tr., 8/29/06, vol. III, 19:11-13.

198 DX 300, '704 patent, Gross Decl., Ex. K, 114:1-4.

199 Trial Tr., 8/29/06, v. III, 13:10-25.

which in the '704 application is 3a, respectively.[200] In the Cha PCT Application, sequence 77 genotypes Type II and sequence 78 genotypes Type III.[201] A person of ordinary skill in the field in 1992 would have understood from reading the Cha PCT Application that Dr. Cha was practicing the method of Claim 5 of the 704 Patent.[202]

Claim 6

Claim 6 requires: "The method of claim 5 wherein at least one probe hybridizes to at least one domain selected from the group of domains consisting of" a list of 13 specified domains.[203] In the PCT Application, sequences 77 and 78 correspond to sequence numbers 24 and 13 in the '704 patent respectively, both of which are listed in Claim 6.[204] Also, sequences of the Cha PCT Application, numbers 33, 45 and 47 are also found in claim 6.[205] A person of ordinary skill in the field in 1992 would have understood from reading the Cha PCT Application that Dr. Cha was practicing the method of Claim 6 of the 704 Patent.[206]

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[200] Trial Tr., 8/29/06, v. III, 13:25-14:3.

[201] Trial Tr., 8/29/06, v. II, 58:17-24; 59:11-15.

[202] Trial Tr., 8/29/06, v. III, 14:4-8. *See also* Defendant Abbott Laboratories' Brief In Support of Its Motion For Summary Judgment, 5/15/06, Dkt. No. 51, incorporated by reference herein, at 39-40, for more discussion of how the Cha PCT Application anticipates Claim 5 of the '704 patent.

[203] DX 300, '704 patent, Gross Decl., Ex. K, 114:5-50.

[204] Trial Tr., 8/29/06, v. II, 17:22-18:3; v. III., 15:8-12.

[205] Trial Tr., 8/29/06, v. III, 15:4-7; 15:14-19; 15:21-25.

[206] Trial Tr., 8/29/06, v. III, 16:1-7. *See also* Defendant Abbott Laboratories' Brief In Support of Its Motion For Summary Judgment, 5/15/06, Dkt. No. 51, incorporated by reference herein, at 40-41, for more discussion of how the Cha PCT Application anticipates Claim 6 of the '704 patent.

Claim 7

Claim 7 requires "The method of claim 6, wherein a first probe hybridizes to one of the domains of claim 6, and wherein a second probe hybridizes to a domain selected from the group of domains consisting of" another list of domains.[207] The same sequences in the Cha PCT Application identified as anticipating claim 6 read on claim 7.[208] The second domain is also listed in the Cha PCT Application.[209] A person of ordinary skill in the field in 1992 would have understood from reading the Cha PCT Application that Dr. Cha was practicing the method of Claim 7 of the 704 Patent.[210]

Claim 8

Claim 8 reads: "The method of Claim 1 further comprising as a control, hybridizing with a universal probe which hybridizes to a domain selected from the group consisting of TTG GGC GYG CCC CCG C (No. 20) and TCT GCG GAA CCG GTG A (No. 27)."[211] The universal probes described in the genotype sequences 33-51 of the Cha PCT Application each read on this claim.[212] A person of ordinary skill in the field in 1992 would have understood from reading the Cha PCT Application that Dr. Cha was practicing the method of Claim 8 of the 704 patent.[213]

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[207] DX 300, '704 patent, Gross Decl., Ex. K, 114:51-115:39.

[208] Trial Tr., 8/29/06, v. III, 15:4-7; 15:8-12; 15:14-19; 15:21-25; 16:9-17:2.

[209] Trial Tr., 8/29/06, v. III, 15:4-7; 15:8-12; 15:14-19; 15:21-25; 16:9-17:2.

[210] Trial Tr., 8/29/06, v. III, 17:4-7. *See also* Defendant Abbott Laboratories' Brief In Support of Its Motion For Summary Judgment, 5/15/06, Dkt. No. 51, incorporated by reference herein, at 41-42, for more discussion of how the Cha PCT Application anticipates Claim 7 of the '704 patent.

[211] DX 300, '704 patent, Gross Decl., Ex. K, 116:1-5.

[212] Trial Tr., 8/29/06, v. III, 20:8-12.

[213] Trial Tr., 8/29/06, v. III, 20:13-17.

Claims 12 and 13

Claim 12 is "The method of claim 1 wherein the probe(s) have been immobilized on a solid support."[214] The Cha PCT Application describes assays that use solid supports and methods of genotyping that use genotyping specific probes from the 5' untranslated region.[215]

Claim 13 is "The method of claim 1 wherein the nucleic acids in the biological sample have been immobilized on a support."[216] The sandwich assay in the PCT Application includes taking the target sequence and fixing that to the support, and thus reads on claim 13.[217]

Claims 12 and Claims 13 of the 704 patent describe techniques of dot blot and reverse dot blot.[218] When the "sandwich" is made between a DNA probe and its target or an RNA probe and its target, either the target sequence can be bound to the piece of paper or the probe sequence can be bound to the piece of paper.[219] Claim 12 is the method of Claim 1 where the probe is immobilized on this solid support, which is usually a special piece of paper,[220] and claim 13 is the method wherein nucleic acids and the biological sample are applied to the paper and then probed.[221] One is the reverse of the other, but binding one of the components of this hybridization complex to the piece of paper.[222] A person of ordinary skill in the field in 1992

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214 DX 300, '704 patent, Gross Decl., Ex. K, 116:34-35.

215 Trial Tr., 8/29/06, vol. III, 18:8-19:19.

216 DX 300, '704 patent, Gross Decl., Ex. K, 116:36-37.

217 Trial Tr., 8/29/06, vol. III, 19:20-22.

218 Trial Tr., 8/29/06, vol. III, 18:8-14.

219 Trial Tr., 8/29/06, vol. III, 18:15-19.

220 Trial Tr., 8/29/06, vol. III, 19:17-19.

221 Trial Tr., 8/29/06, vol. III, 19:20-22.

222 Trial Tr., 8/29/06, vol. III, 19:22-24.

would have understood from reading the Cha PCT Application that Dr. Cha was practicing the method of Claims 12 and 13 of the '704 patent.[223]

There was substantial evidence that although the Cha PCT Application was provided to the U.S. examiner reviewing the '704 patent application, it may have very well not been considered by her. First, the Prior Art statement Innogenetics filed along with the International Search Report that listed the Cha PCT reference stated that it (among other references) did "not relate to the invention and, therefore, further discussion of the same is not necessary."[224] Second, the patent examiner filled out a Form 892 upon which she listed a Cha article but not the Cha PCT Application.[225] Third, the inventor interview attended by the examiner, the inventor and his counsel, did not include discussion of the Cha PCT Application.[226] Finally, the '704 patent itself does not bear any mention of the Cha PCT application.[227]

2. As Innogenetics and Dr. Maertens Both Admitted, The '704 Patent's Use Of Probes 77 and 78 in the 5' UTR To Specifically Hybridize Was First Invented By Cha And Disclosed In The Cha PCT Application, Which Thus Anticipated It

The inventors of the '704 patent claimed that they had first discovered the genotype-specific sequences in the 5'UTR, including sequence ID No. 13.[228] This supposed discovery was part of the only independent claim in the '704 patent, claim 1: "specifically

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[223] Trial Tr., 8/29/06, vol. III, 19:25-20:4.

[224] Opinion and Order, 7/17/06, Dkt. No. 131, at 4.

[225] Opinion and Order, 7/17/06, Dkt. No. 131, at 6.

[226] Opinion and Order, 7/17/06, Dkt. No. 131, at 10.

[227] DX. 300, '704 Patent, Gross Decl., Ex. K, col. 39 (Table 4).

[228] DX. 300, '704 Patent, Gross Decl., Ex. K, col. 39 (Table 4).

hybridizing a probe to a domain extending from minus 291 to minus 66 of the 5' UTR region of hepatitis C."[229]

Innogenetics' counsel now stands before this Court and argues that Abbott should be punished for having no invalidity case, but it fails to mention two key facts: First, Innogenetics stipulated during trial that the Cha PCT Application disclosed the '704 patent's Sequence ID 13: "Innogenetics does not dispute that Sequence AATCGCTGGGGTGACC is Sequence ID 78 in the Cha application, Cha PCT application, and Sequence No. 13 in the '704 patent."[230]

Perhaps counsel has the same bad memory as Dr. Maertens. On the stand, Dr. Maertens refused to admit that Innogenetics was not the first to identify sequence 13 as a genotype-specific sequence. It was only when he was confronted with the stipulated admission above that he admitted they had made no such invention:

Q. "Dr. Maertens, Innogenetics wasn't the first to identify sequence 13 as a genotype-specific sequence, was it?"
A. "I think it was."
Q. "You've been in the courtroom this whole trial, have you?"
A. "Yes."
Q. "Did you hear me yesterday read into the record, based on a stipulation made by your counsel, that sequence 13 listed here on Table 4 is sequence 78 in the Cha PCT application?"
A. "I heard something like that, yes."
Q. "And so isn't it correct that sequence 13 in the '704 patent had already been identified by Dr. Cha?"
A. "I don't know whether it's the same sequence. I will have to verify that.
Q. "Well, you heard the stipulation, didn't you?"
A. "If that's true, then the same sequence had probably been identified, yes."[231]

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[229] Trial Tr., 8/29/06, v. II, 52:19-23.

[230] Trial Tr., 8/29/06, v. II, 18:1-3.

[231] Trial Tr. 8/30/06, v. III, 60:2-18.

Each of these facts reveals the falsity of Innogenetics' arguments about the evidence in this case and shows additional support for Abbott's invalidity case.

3. Abbott Was Prepared To Present Testimony From Dr. Cha That Would Have Established The Anticipation And Obviousness Of The '704 Patent In Light Of The Cha PCT Application

(a) As Innogenetics' Counsel Itself Vigorously Argued, Dr. Cha's Excluded Testimony Was Not Just Relevant; It Would Have Shown Beyond Question That The Cha PCT Application Was Enabling, Anticipatory And Rendered The '704 Patent Obvious

The author of a prior art article may testify to what he intended to teach based on his personal knowledge as one of ordinary skill in the art. *Gambro Lundia AB v. Baxter Healthcare Corp.*, 110 F.3d 1573, 1577-1579 (Fed. Cir. 1997); *see also In re Omeprazole Patent Litig.*, 2002 WL 287785 at *6 (S.D.N.Y. 2002) ("fact witnesses who are skilled in the art ... are competent to testify concerning prior art documents"). Dr. Cha, an author of several prior art references in the case, including the Cha PCT Application, was therefore entitled to "describe the nature of his work as reflected in four prior art references, explain his experiments, analyses and results and generally inform the jury about his work"[232] as a fact witness.

This fact testimony of Dr. Cha, as a prior art inventor, was highly relevant to anticipation, and certainly relevant to explaining how the disclosures in his own PCT Application would have been understood by a person of ordinary skill in the art at the relevant time. This was not lost on Innogenetics, whose counsel argued that

[232] Opposition to Innogenetics' Motion In Limine To Exclude the Testimony of Dr. Tai-An Cha and Any Expert Testimony of Dr. Thomas White, ("Oppo. to Motion in Limine Re Cha and White"), 8/16/06, Dkt. No. 241, at 6.

> . . . . . *whether or not you can design probes and know the conditions and understand how to do it and whether it was known in the art is very, very relevant to whether the Cha PCT is indeed enabled.* Dr. Cha has just testified and is going to testify, I fear, that his work is building upon results that led to the Cha PCT Application. If we allow him to start talking about it, it's going to be very confusing for the jury to then draw the line between the Cha PCT and an undisclosed body of work. . . . *Dr. Cha is going to march through all of his knowledge and experience in front of the jury which goes to the heart of enablement which their expert didn't opine on. It is what one of ordinary skill in the art would understand.* . . . Now Dr. Cha is asked to testify across his career over a body of work that includes several references, all of which have discrete disclosures in them that if combined will *give the impression that one of ordinary skill in the art would assume that example two of the Cha PCT is enabled simply because of the knowledge that was available to one of ordinary skill in the art.* . . .[233]

Plaintiff's counsel also sought to curtail Dr. Cha's testimony because the disclosures of the Cha PCT Application were so compelling that even without opinion testimony about "obviousness," the jury could easily conclude that the patent-in-suit was invalid for obviousness:

> If Abbott is going to seek testimony on his body of work, that gives the inherent perception that that combination of his body of work, *which we all know would fall under the obviousness standard, would indeed invalidate the '704 patent* and failure to use the words such as enablement and '704 and what is your opinion are not the issue. The issue is that that knowledge will be conveyed to the jury through Dr. Cha's testimony regardless of the use of those words.[234]

For both of these reasons, Innogenetics warned the Court that such testimony was "highly prejudicial" to it.[235]

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[233] Trial Tr., 8/29/06, v. I, 62:10-18, 66:7-11, 72:2-9 (emphasis added).

[234] Trial Tr., 8/29/06, v. I, 69:18-70:2.

[235] Trial Tr., 8/29/06, v. I, 70:2; 72:10-11.

Indeed, Dr. Cha's testimony would have been justifiably "prejudicial" to Innogenetics' case, but it was ***unfairly prejudicial*** to Abbott to exclude it. Having the jury understand the Cha PCT Application was crucial to Abbott's anticipation, and what would have been its obviousness, position. It disclosed all of the elements of the patent-in-suit, and had priority.[236] Excluding Dr. Cha's testimony about the state of the art at the time, and what the Cha PCT Application disclosed in light of that state of the art, ensured that the jury would have difficulty finding the disclosures in the two highly technical references. As the Court put it, Dr. Cha was "the very heart, the center of this whole case."[237]

In addition, Dr. Cha's testimony about persons of ordinary skill in the art, and their knowledge in the relevant time period, would have been very helpful to the jury on a number of other broader issues. *See* Abbott Laboratories' Proposed Jury Instructions For Liability Phase of Trial, at 13 (determining the level of ordinary skill in the art); *id.* at 29-30 (determining whether prior art reference inherently anticipates) (*citing* AIPLA Jury Instruction 6.0); *id.* at 31-32 (enablement to one of ordinary skill in the art) (*citing* AIPLA Jury Instruction 6.4). *See also Novo Nordisk Pharms., Inc. v. Bio-Tech. Gen. Corp.*, 424 F.3d 1357, 1355 (Fed. Cir. 2005) ("anticipation requires that those suggestions be enabled to one skilled in the art").

(b) <u>It Was Not Abbott's Fault That It Could Not Present This Crucial Testimony To The Jury</u>

On August 18, 2006, the Court denied Innogenetics' motion to exclude Dr. Cha's testimony but stated that his testimony would be "restricted to descriptions of the work [he] did and [his] observations; [he] may not elaborate on [his] observations, explain anomalous results or

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[236] DX 300, '704 patent, Gross Decl., Ex. K, Claims 1-8, 12, 13; Fig 4; DX 303, Cha PCT Application, Gross Decl., Ex. D, 2:9-20; 9; 11:10-13; 12:7-20; 21:1-9; 36 (Table 1); 37:22-25; 38:9-15; 41:26-42:1; 42; 43 (Table 4); 49; 78-95; 136-39.

testify as [an] expert[]."[238] Yet, when Dr. Cha took the stand, with the exception of a few statements about his work, the Court excluded all of Dr. Cha's testimony except his reading directly from the PCT Application.[239]

As the Court expressed it, Dr. Cha could not testify at all about his PCT Application, or about aspects of his work related to the prior art because the jury had to decide anticipation based on what was within the four corners of the PCT Application:

> It's clear to me that Dr. Cha's testimony at this point about what he did, and how he finally got to the ideas that were incorporated into his application is going to be confusing to the jury and completely irrelevant because the jury, when it comes down to it, the jury has to decide this solely on what was available in the application itself.[240]

Because of his scientific, technical and other specialized knowledge, Dr. Cha was disclosed to Innogenetics' counsel pursuant to Fed. R. Civ. P. 26(a)(2)(A) as an expert who had not been specially retained.[241] Nevertheless, Innogenetics purposefully avoided deposing

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[237] Pretrial Conf. Tr., 8/17/06, Dkt. No. 260, 45:17-18.

[238] *See* Pretrial Order, 8/18/06, Dkt. No. 256, at 3 ("Motion to exclude testimony of Dr. Cha and Dr. White. DENIED. However, both witness are restricted to descriptions of the work they did and their observations; they may not elaborate on their observations, explain anomalous results or testify as experts"). At first, the Court had agreed that Dr. Cha could properly provide testimony about his own personal work and observations. He was not to provide testimony on "what someone of ordinary skill in the art would read into" the PCT Application, nor was he to offer opinions as to the ultimate conclusions in the case, for example, that the PCT Application anticipated the patent-in-suit. Pretrial Conf. Tr., 8/17/06, Dkt. No. 260, 43:7-44:21. But even as to his own personal observations, for example, if he observed an anomaly in the course of his work, the Court cryptically ruled that testimony to that effect was off-limits. The Court's explanation: "you took a real chance not to name him as an expert witness and this is the price you have to pay. . . . that's the way it's going to be." Pretrial Conf. Tr., 8/17/06, Dkt. No. 260, 45:24-46:20.

[239] Trial Tr., 8/29/06, v. II, 3:6-5:9; 7:25-15:3 (reading excerpts from PCT Application).

[240] Trial Tr., 8/29/06, v. II, 3:6-11.

[241] Opposition to Motion in Limine Re Cha and White, 8/16/06, Dkt. No. 241, at 1.

Dr. Cha so they could later and wrongfully claim prejudice.[242] Also, contrary to the Court's views, the fact that Dr. Cha has scientific, technical and other specialized knowledge and expertise does not mean he has to produce a written report in order to testify. Rule 26(a)(2)(B) only requires a written report from "witnesses who are retained or specially employed to provide expert testimony in the case; and witnesses whose duties as an employee of the party regularly involve giving expert testimony."[243] Dr. Cha was in neither of these categories.[244]

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[242] The Court's reasoning in excluding Dr. Cha's testimony ostensibly included concerns that Innogenetics had somehow been or would be surprised by his testimony at trial. Nothing could have been further from the truth. Dr. Cha was disclosed in expert witness disclosures in April of 2006 as a non-retained expert and in that disclosure, his expertise, his background and testimony were specified. (*See* Abbott Laboratories' Proponent Expert Witness Disclosures, 4/10/06, Dkt. No. 32, at 1-3.) Dr. Cha was also disclosed to Innogenetics, even before Abbott knew his name, in November of 2005, in Defendant's rule 26(a)(1) Initial Disclosures, with sufficient information for Innogenetics to find him. Finally, on July 28, 2006, Dr. Cha was again disclosed in Abbott's section 282 notice as one of the persons "who may be relied upon as prior inventors or having knowledge of or as having previously used or offered for sale the invention of the patent-in-suit". Innogenetics argued that although it had information to reach Dr. Cha all along, it purposely avoided deposing him and finding out what he had to say, expecting that the Court would hold ***Innogenetics'*** failure to depose Dr. Cha against ***Abbott*** (Pretrial Conf. Tr., 8/17/06, Dkt. No. 260, 33:12-34:1), which indeed the Court did. (Pretrial Conf. Tr., Dkt. No. 260, 45:24-46:1.)

[243] *See* Fed. R. Civ. P. advisory committee's notes on 1993 amendment, subd. (a) ¶ 2 (West 2006), ("For convenience, this rule and revised Rule 30 continue to use the term 'expert' to refer to those persons who will testify under Rule 702 of the Federal Rules of Evidence with respect to scientific, technical , and other specialized matters. The requirement of a written report in paragraph (2)(B), however, applies only to those experts who are retained or specially employed to provide such testimony in the case or whose duties as an employee of a party regularly involve the giving of such testimony").

In its brief, Innogenetics argues that Abbott should be punished for its many "Rule 26" violations. One of these is its purported failure to have Dr. Cha prepare a report disclosing his opinions pursuant to Rule 26. Motion, at 20. But since Rule 26 did not require a report to be furnished by Dr. Cha, his not doing so cannot be considered a "violation."

[244] Pretrial Conf. Tr., 8/17/06, Dkt. No. 260, 42:12-43:2 (Dr. Cha was not paid for his testimony); Innogenetics' Motion In Limine To Exclude the Testimony of Dr. Tai-An Cha and Any Expert Testimony of Dr. Thomas White, 8/10/06, Dkt. No. 190, ("Motion in Limine Re Cha (footnote continued)

When asked whether the Court's "ruling [would] exclude Dr. Cha's discussion of the work he did that is described in the PCT Application," the Court answered:

> Court: Yes. If it, other than just reading what it says because his explanation was not available to anyone at Innogenetics when they were doing their work.
>
> [D's Atty]: I believe, Your Honor, as a matter of fact, his explanation in the body of work he created was available and would be part of that extrinsic evidence that would inform an analysis of the PCT Application. . . . his body of work, including published articles were available at the time and would have been the sort of extrinsic evidence that one would consider when approaching an analysis of an anticipated piece of prior art.
>
> Court: Well, then the expert, anyone who has testified to that in the past and has made that known to the plaintiff can testify about that, but Dr. Cha can't.
>
> [D's Atty]: Except Dr. Cha? Except Dr. Cha, who was disclosed?
>
> Court: Dr. Cha can't testify about that. That would be essentially telling the jury what persons of ordinary skill in the art would have known at the time they read his application and he was not disclosed as an expert to talk about that subject.[245]

Thus, the Court clearly erred by precluding Dr. Cha's testimony explaining the Cha PCT Application. The Federal Circuit has made clear that it is error to merely present the reference with no explanatory testimony to explain how a person of ordinary skill in the art would have understood its disclosures. *Koito v. TurnKey Tech***,** 381 F.3d 1142, 1152 (Fed Cir. 2004) ("We have consistently explained what is necessary to show anticipation by a given reference. Typically, testimony concerning anticipation must be testimony from one skilled in the art and must identify each claim element, state the witness's interpretation of the claim element, and explain in detail how each claim element is disclosed in the prior art reference. The

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and White") at 4 (acknowledging that Dr. Cha is an independent witness that was not paid); Trial Tr., 8/29/06, v. I, 56:21-57:3 (testified that he was not employed by or affiliated with any of the parties).

[245] Trial Tr., 8/29/06, v. II, 4:3-25.

testimony is insufficient if it is merely conclusory.") (*citing Schumer v. Lab. Computer Sys., Inc.*, 308 F.3d 1304, 1315-16 (Fed. Cir. 2002)). *See also Telemac Cellular v. Topp Telecom*, 247 F.3d 1316 (Fed. Cir. 2001) (extrinsic evidence - a patent and informal invention disclosure of the plaintiff, along with the inventor's admissions about what persons of ordinary skill in the art would have known are admissible to establish a prior art reference as anticipatory); *In re Baxter Travenol Labs.*, 952 F.2d 388, 390 (Fed. Cir. 1991) ("extrinsic evidence [such as depositions, declarations, and admissions] may be considered when it is used to explain, but not expand, the meaning of a reference. . . . Here, the depositions and declarations of skilled workers and Baxter's admissions were used to identify what materials Baxter's commercial bags contained at the time of the [prior art reference], thereby explaining what the phrase '[Baxter] Travenol's commercial, two blood bag container' would have meant to one skilled in the art. This evidence clearly shows that those skilled in the art, reading the Becker document, would have known that Becker's primary bag was plasticized with DEHP." (*citing Scripps Clinic & Research Foundation v. Genentech, Inc.*, 927 F.2d 1565, 1576-77 (Fed. Cir. 1991))).[246]

[246] Indeed, this Court has previously acknowledged that is error not to provide the jury with testimony that would allow it to properly evaluate an anticipatory reference. "Although defendant's anticipation argument relied in part on an article by Lyamichev, Brow and Dahlberg, "Cleavage-Specific Endonucleolytic Cleavage of Nucleic Acids by Eubacterial DNA Polymerases,' published in *Science* in 1993, defendant never called a witness at trial to testify about the article's contents, leaving the jury without any way of evaluating the article's relevance to the '314 patent." *Third Wave Techs., Inc. v. Stratagene Corp.*, 405 F. Supp. 2d 991, 1005-06 (W.D. Wis. 2005). In fact, the Court acknowledged at the pretrial conference that it has "always allowed inventors to talk about what they did, how they invented their method, product, whatever it is." Pretrial Conf. Tr., 8/17/06, Dkt. No. 260, 31:24-32:2.

4. Abbott Had Other Sources Of Evidence On Enablement Available To It Throughout The Case That Were Improperly Excluded From Trial

Innogenetics complains that Abbott did not have any legitimate evidentiary basis upon which to show that the Cha PCT Application was enabled. Nothing could be further from the truth.

First, Abbott came to trial with Dr. Patterson, whose expert report included extensive material pertinent to the enablement issue. Dr. Patterson established himself as a person of ordinary skill in the art and wrote his report from that perspective;[247] he had a long description devoted to Cha's work and its significance;[248] he described numerous prior art references in detail and explained what they taught to those of ordinary skill in the art;[249] and he described the state of the art in 1992, including a description of the kinds of techniques that a person of ordinary skill in the art at the relevant time would have known.[250] All of these disclosures went to the heart of the enablement question. *See Minnesota Min. & Mfg. Co v. Chemque, Inc.*, 303 F.3d 1294, 1306 (Fed. Cir. 2002) ("In order to enable, the prior art reference must teach one of ordinary skill in the art to make or carry out the claimed invention without undue experimentation"); *see also* ABA Model Jury Instructions, Section 9.2.1 Enablement ("The written description of the invention claimed in a patent must contain enough detail to teach, or enable, persons skilled in the field to make and use the invention").[251]

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[247] Patterson Invalidity Expert Report, 4/10/06, Dkt. No. 33, at 1-2.

[248] *Id.*, at 9-14.

[249] *Id.*, at 21-23.

[250] *Id.*, at 3-9; 21-23.

[251] Post-Trial Instructions, 9/1/01, Dkt. No. 328, at 6.

Innogenetics pretends that Abbott should have known as it approached trial that Dr. Patterson's opinions, fully disclosed in advance pursuant to Rule 26, were to be chopped up and in large part excluded. But Abbott was not given any warning. Before the trial began, the Court ruled in response to Innogenetics' motion in limine that: "3. Motion to exclude Patterson testimony on issue of anticipation as it relates to enablement. GRANTED as to anything Patterson did not disclose in his expert report."[252] Since Dr. Patterson had disclosed a great deal that was pertinent to enablement, this ruling should not have affected his planned testimony at all.

But for some reason, Dr. Patterson's expert report was turned from essentially a discovery document prepared to give notice to an opposing party and expert to a closed and fixed menu of items Dr. Patterson was allowed to mention. The scope of Dr. Patterson's testimony became an oddly pervasive theme throughout the proceedings.[253] And the Court actively policed Dr. Patterson to make sure he didn't "stray." Even on rebuttal, Dr. Patterson was only allowed to respond to plaintiff's expert's testimony if he had "talked about this in his initial testimony."[254] The Court went so far as to prevent Dr. Patterson from responding with an explanation to a

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[252] Pretrial Order, August 18, 2006, at 3.

[253] Pretrial Conf. Tr., 8/17/06, Dkt. No. 260, 25:17-18 ("He won't be allowed to testify about things he hasn't covered in his report"); Pretrial Conf. Tr., 8/17/06, Dkt. No. 260, 29:4-5 ("It's limited to anything that he has not disclosed in his report"); Trial Tr. 8/29/06, v. II, 73:15-16 ("If he doesn't say anything beyond what he says in his written report, that's fine. . . . but he can't go beyond that"); Trial Tr., 8/29/06, v. II, 78:2-3 ("I hope that he doesn't stray from what he said in his report").

[254] Trial Tr., 8/31/06, v. I, 70:15-17.

criticism by plaintiff's expert, Dr. Worman, and refused to allow him to explain that the irrelevant matter was not part of his report because it was, in fact, irrelevant.[255]

Abbott also planned to present Dr. Cha's '693 patent on the subject of enablement. The '693 patent had an identical specification to that of the Cha PCT application. Unlike the Cha PCT Application, it enjoyed a presumption of enablement that Innogenetics was required to rebut with clear and convincing evidence. *See Amgen v. Hoechst Marion*, 314 F.3d 1313, 1355 (Fed. Cir. 2003). But it, too, was improperly excluded by the Court.

The '693 patent was first raised by Innogenetics when its expert, Mr. Sofocleous, provided an expert report, much of which was devoted to "The Prosecution History of Cha et al. U.S. Patent No. 6,071,693." In this report, Mr. Sofocleous stated that he had "reviewed a copy of the prosecution history" of that patent, and that it "contains the same specification (disclosure) as the Cha PCT Application."[256] Innogenetics used the evidence of Cha's '693 patent and its prosecution history, and its expert's opinions about them, to pursue an argument on summary judgment at some length.[257]

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[255] Trial Tr., 8/31/06, v. II, 15:8-16:18 ([D's atty]: "But now that we've heard an hour-and-a-half of testimony by Dr. Worman, . . . he spent an hour-and-a-half up there yesterday and we can't even tell the jury why Dr. Patterson didn't even look at those, that's crazy." Court: "Well, it may be crazy, but that's what the ruling is.". . . Court: "We'll have him come over here so I can instruct him." [D's atty]: "Do you want to tell him? The Judge is going to ask you a question." Court: "All right. Mr. McIntyre is going to ask you a question. Why don't you read it." [D's atty]: "With respect to the probe-based assay in the Cha PCT Application, why did you focus on probes 77 and 78?" Court: "Don't answer, you'll get a chance on the witness stand. What I'm saying is you are not to discuss probe 73 and 74 in answering that question." Witness: "Yes, Your Honor").

[256] Expert Report of Michael Sofocleous, Dkt. No. 43, at 38, ¶114.

[257] Brief In Support of Motion For Summary Judgment of No Inequitable Conduct, Dkt. No. 47, at 27-31.

Abbott formally disclosed its reliance on the '693 patent in its notice pursuant to 35 U.S.C. § 282, which it timely served on July 28, 2006, and its Amended 282 Notice, which was served on July 31, 2006.[258]

The Court's proposed jury instructions, circulated to the parties before the first day of trial, specifically identified the '693 patent as an item of anticipatory prior art.[259] Further on in the instructions, the '693 was noted again as a piece of prior art being considered by Abbott for obviousness purposes:

> The prior art that you considered previously for anticipation purposes is also prior art for obviousness purposes. The prior art includes the following items received into evidence during the trial: . . . the Cha '693 Patent.[260]

The Court's instructions were based on jury instructions timely submitted by Abbott. Abbott's proposed jury instructions had followed this same pattern in identifying the '693 patent as a possible anticipatory reference, and instructed the jury on anticipation under section 102(e)(2), but Abbott did not include the '693 patent in an additional separate proposed instruction on anticipation.[261]

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[258] Abbott Laboratories' Notice Pursuant to 35 U.S.C. § 282, dated July 28, 2006, Gross Decl., Ex. L, at 2;Abbott Laboratories' Amended Notice Pursuant to 35 U.S.C. § 282, dated July 31, 2006, Gross Decl. Ex. M, at 2.

[259] Abbott Laboratories' Proposed Jury Instructions For Liability Phase of Trial, 8/10/06, Dkt. No. 180, at 27.

[260] Court's Proposed Jury Instruction, Gross Decl. Ex. N. at 13-18.

[261] Abbott Laboratories' Proposed Jury Instructions For Liability Phase of Trial, 8/10/06, Dkt. No. 180, at 36. It was in the limited context of this one jury instruction from which it was omitted that Abbott's counsel made his statement about "inadvertence" in not including reference to the '693. Innogenetics suggests in its brief (at 25) that this was an admission that Abbott had "not . . . raised [it] earlier" anywhere although that is not true.

On the first day of trial, Abbott requested that the Court amend its jury instruction on anticipation to explicitly reference the Cha '693 patent, but the Court refused and struck the reference entirely from Abbott's case instead:

> Court: Everything that you disclosed before, the Lee article, the Resnick patent and the Cha PCT Application are fair game, but the '693 patent you would not disclose to the plaintiff as a single source of anticipation of the '704 patent.
>
> [D's Atty]: With all due respect, your honor, we did provide the plaintiff with a Sec. 282 notice that disclosed the '693 patent on July 27th, 2006.
>
> Court: I know that.
>
> [D's Atty]: And you're saying that despite that disclosure, under the U.S. Patent Code the Court will not permit us to rely on the '693 as an anticipating reference?
>
> Court: That's what I'm ruling.[262]

The basis of the Court's ruling purported to be the potential for undue prejudice to Innogenetics resulting from Abbott's supposed failure to disclose the '693 in a timely way, which was clearly erroneous. The primary error is, of course, that it in fact *was* disclosed in a timely and appropriate way. This is evidenced not only by the Section 282 notice, but by Abbott's and the Court's own proposed jury instructions.

The Court's view that Innogenetics would be unfairly prejudiced by allowing Abbott to proceed with establishing the anticipation of the '704 patent by the '693 patent was also erroneous. Also, Abbott's timely Section 282 notice was presumptively sufficient to prevent undue surprise. The purpose of Section 282, which requires parties to disclose the prior art they are relying on *thirty* days before trial, is "to prevent patentees being surprised, at the trial of the cause, by evidence of a nature which they could not be presumed to know, or be prepared to

[262] Trial Tr., 8/28/06, v. I, 84:15-85:3.

meet, and thereby to subject them either to most expensive delays, or to a loss of their cause." *Philadelphia & Trenton Railroad Co. v. Stimpson*, 39 U.S. 448, 459 (1840). *See, e.g., Trans-World Mfg. Corp. v. Al Nyman & Sons, Inc.*, 750 F.2d 1552, 1561-62 (Fed. Cir. 1984). The '693 patent was in the Court's own jury instructions as an anticipatory reference when the Court decided to strike it.

Second, even had there been no disclosure of the '693 patent, Innogenetics knew all about this reference and was fully prepared to counter arguments based on it. This was a reference that Innogenetics' own technical expert raised, analyzed, and argued on Innogenetics' behalf in this case. In addition, it was a reference with the same disclosure as the Cha PCT Application, which was already the subject of an existing anticipation defense by Abbott, and the subject of expert testimony to be presented by Innogenetics' experts, Dr. Worman and Dr. Reznikoff.[263]

The restrictions on Dr. Cha's and Dr. Patterson's testimony on the subject of enablement, and the total exclusion of the '693 patent, all constituted substantial prejudicial errors on the part of the Court.[264] Had the Court not made these rulings, Abbott would have been

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[263] Trial Tr., 8/30/06, v. I, 48:2-51:20; 56:15-75:24; v. II, 3:23-114:11; 20:1-24:33; 27:16-28:8; 30:14-33:6.

[264] Another one of the supposed "Rule 26" violations that Innogenetics argues that Abbott should be punished for is its purported failure to have Dr. Patterson disclose his opinions on enablement pursuant to Rule 26. Motion, at 20. But since Dr. Patterson in fact did disclose his opinions on enablement pursuant to Rule 26, there is no "violation."

A third supposed violation of Rule 26 Innogenetics raises in its brief was Abbott's challenge of the completeness of projections for the long-term value of its HCV genotyping products. Motion, at 21. Again, this is simply not a violation. It was perfectly appropriate for Abbott to elicit testimony to prevent the jury from laboring under a factual mistake concerning the exhibit. Trial Tr., 9/7/06, v. III, 5:12-21; 9/8/06, v. II, 26:17-27:9. That Innogenetics, and ultimately the Court, preferred for the jury not to have the complete facts is simply wrong.

able to present a great deal of evidence supporting its view that the Cha PCT Application was enabled.

And this evidence would have been particularly probative in light of the purported "expert" testimony that was presented by Innogenetics on enablement. Innogenetics' two experts each testified extensively on the Cha PCT's alleged lack of enablement even though they had no factual basis for doing so. Dr. Worman testified about the level of experimentation necessary to carry out specific hybridization;[265] how it was "impossible to conclude"[266] that a person of ordinary skill in the art could get the desired results from reading what was in the Cha PCT Application; that Cha got "useless results;" [267] and that certain results would call into question other results.[268] Dr. Reznikoff then testified broadly about the insufficiency of the PCT Application's disclosures;[269] his inability to tell whether or not Dr. Cha himself had achieved specific hybridization;[270] and the general impossibility of being able to carry out specific hybridization using the technique disclosed.[271]

But Dr. Worman had not successfully or reproducibly run any assays himself.[272] Nor did he consult any of the instructive technical references listed in the PCT Application or otherwise in arriving at his opinion.[273] Dr. Reznikoff was no better. He did not test his own

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[265] Trial Tr., 8/30/06, v. I, 42:3-5.

[266] Trial Tr., 8/30/06, v. I, 60:18-61:1.

[267] Trial Tr., 8/30/06, v. I, 67:7-20.

[268] Trial Tr., 8/30/06, v. I, 61:2-64:4; 68:12-21.

[269] Trial Tr., 8/31/06, v. I, 41:1-42:5.

[270] Trial Tr., 8/31/06, v. I, 39:15-23

[271] Trial Tr., 8/31/06, v. I, 40:10-20.

[272] Trial Tr., 8/30/06, v. II, 35:20-37:15.

[273] Trial Tr., 8/30/06, v. II, 63:1-64:25; v. III, 3:18-21.

theory in the lab in preparing his opinion.[274] Nor did he test his own theory with respect to the PCT Application.[275] He had, in fact, no clinical laboratory experience,[276] no knowledge of hepatitis C before this case,[277] and no knowledge of hepatitis C prior art in 1992.[278] He did not review any of the references listed in the PCT Application.[279] He has never genotyped HCV[280] and did not try to duplicate the genotyping analysis described in the PCT Application in the course of his work on the case.[281] And he did not test his conclusions to see if they were correct.[282] It was truly Innogenetics, not Abbott, that was "wholly lacking on the subject of enablement."[283]

B. The Cha '693 And Resnick '718 References, Both Ultimately Disposed Of By Erroneous Court Rulings, Also Supported Abbott's Good Faith Arguments That The '704 Patent was Anticipated And Rendered Obvious

Besides providing evidence of enablement, the Cha '693 patent was an anticipating reference pursuant to 35 U.S.C. § 102(e). As mentioned above, the Court's exclusion of this entire reference from trial on the purported basis of untimeliness, when in fact the '693 patent had been timely disclosed as an anticipatory reference and was already well known to Innogenetics, was made over Abbott's objection.

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274 Trial Tr., 8/31/06, v. I, 42:13-21.

275 Trial Tr., 8/31/06, v. I, 42:13-21.

276 Trial Tr., 8/31/06, v. I, 43:15-17.

277 Trial Tr., 8/31/06, v. I, 44:2-5.

278 Trial Tr., 8/31/06, v. I, 44:9-11.

279 Trial Tr., 8/31/06, v. I, 45:3-46.1.

280 Trial Tr., 8/31/06, v. I, 50:14-15.

281 Trial Tr., 8/31/06, v. I, 50:16-19.

282 Trial Tr., 8/31/06, v. I, 50:20-51:16.

283 Motion, at 13.

There was also ample evidence available to Abbott that could support a finding of anticipation by the Resnick '718 patent. The construction of two claim terms formed the basis for the Court's entry of judgment on this invalidity issue. First, the Court construed "method of genotyping," the preamble language common to all of the method claims of the '704 patent, to mean a "method that distinguishes among types and/or subtypes of hepatitis C virus (HCV) and classifies the HCV into a genotype or subtype."[284] Second, the Court construed "specifically hybridizing" to mean "hybridizing a probe to a target sequence and not to a non-target sequence."[285]

Dr. Patterson testified that the '718 patent disclosed a probe-based method of genotyping that used probes specifically hybridizing to the 5' untranslated region of the HCV genome, and thus that it satisfied these and the other limitations of claim 1:

> Q: … Dr. Patterson, could you briefly describe for us the – what the 718 Patent discloses and teaches?
>
> A: The 718 patent discloses *methods of distinguishing hepatitis C genotypes* by means of PCR-based assay and *probe hybridization in a 5' UT* of the hepatitis C geno[me].
>
> Q: And the domain identified in Claim 1 is between -291 to -66?
>
> A: Yes.
>
> Q: And how do you know that from reading the 718 Patent?
>
> A: By doing a sequence alignment to the primers and probes discussed in my report.
>
> …
>
> Q: Could you explain what Table 1 depicts from the 718 Patent?

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[284] Opinion and Order, 8/11/06, Dkt. 218, at 31.

[285] Opinion and Order, 8/11/06, Dkt. 218, at 22, 31.

A: Table 1 [of the '718 patent] depicts both primers and probes used for the analysis in the 718 Patent, and in particular, as highlighted *Probe No. 8, which falls within the 5' UT*.

Q: Between -291 and –[]66?

A: Yes, it does.

…

Q: … So with respect to Claim 1 of the 704 Patent, is it your opinion that a person of ordinary skill in the field in 1992 would have understood from reading the 718 Patent that Dr. Resnick and his colleagues were practicing the method of Claim 1?

A: Yes.

Q: And why is that? What can you point to in the 718 Patent that would disclose to a person of ordinary skill this information?

A: In the 718 Patent they use probes and primers described in this patent. In particular, Probe No. 8 as shown on the screen, to really *distinguish* between *true groups* of hepatitis C isolates, one containing hepatitis C 1, which is the prototypic strain, and the one that requires a prolonged treatment course for a potential cure, and then *the other group* that's distinguished by this probe are the non-1 types of hepatitis C.

Q: Okay. And is it your opinion that the 718 Patent discloses and teaches each and every element of Claim 1 of the 714 Patent?

A: Yes, it does.[286]

Dr. Patterson thus testified that the Resnick patent disclosed a method of genotyping as claimed in claim 1 of the '704 patent, using a probe targeting the 5' untranslated region, to distinguish between "true groups" of HCV containing type 1, the "prototypic strain," and another group known as "non-1 types of hepatitis C." Dr. Patterson further testified that through its disclosure of PCR amplification before probe hybridization and the use of "dot

[286] Trial Tr., 8/29/06, v. III, 21:17-24:8 (emphasis added).

[b]lots" and "reverse dot [b]lots," the '718 patent also anticipates claims 9, 12 and 13, respectively (each of which depends from claim 1).[287]

Plaintiff's central argument to the Court in moving for judgment as a matter of law was that "the proof on Resnick was based on an erroneous definition of method of genotyping as well as specifically hybridizing."[288] The Court provided its claim construction with its summary judgment ruling on August 11, 2006. Dr. Patterson's expert reports were provided on or around April 10, 2006[289] and May 2, 2006.[290] Dr. Patterson specifically reserved the right to adjust his opinions in light of a claim construction ruling.[291] Although the Court's claim construction occurred months after the expert disclosure deadlines, the Court made explicit that "there shall be no third round of rebuttal expert reports," and that any "[s]upplementation … is limited to matters raised in an expert's first report …."[292] Nonetheless, the Court entered judgment as a matter of law that the '718 patent did not anticipate any claims of the '704 patent on the grounds that Dr. Patterson's opinions at trial were not based on the Court's claim construction, but on his own. After hearing oral argument from both parties, the Court ruled:

> THE COURT: I'll grant the motion as it covers the Resnick '718 patent.
>
> MR. MCINTYRE: Just note our objection, Your Honor.

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287 Trial Tr., 8/29/06, v. III, 25:8-27:22.

288 Trial Tr., 8/31/06, v. II, 25:17-19.

289 Patterson Invalidity Expert Report, 4/10/06, Dkt. No. 33.

290 Patterson Non-Infringement Expert Report, 5/2/06, Dkt. No. 39.

291 Patterson Invalidity Expert Report, 4/10/06, Dkt. No. 33, at 1.

292 Preliminary Pre-trial Conference Order, 11/25/05, Dkt. No. 12.

THE COURT: All right. I am convinced that Dr. Patterson's testimony was based on his opinion about how the claims could be construed, which is not what I concluded. All right.[293]

But the evidence showed, with respect to the claim terms "method of genotyping" and "specifically hybridizing," that Dr. Patterson did not limit his opinions or his testimony at trial to the definitions of those terms that he had provided before the Court had construed them. When plaintiff's counsel attempted to impeach Dr. Patterson on these claim construction issues, Dr. Patterson did not testify that his opinions or testimony at trial were so limited; he merely confirmed that his opinions *in his reports* filed months earlier were based on his own interpretation of the claim language:

Q: … It was on the basis of [your report's] definition of genotyping that the 718 Patent anticipated the claims that you listed for Mr. McIntyre, correct?

A: I think it's encompassed in that sentence.

Q: So the answer is yes?

A: Well, we've already had a definition of genotyping.

Q: Yes. And the definition that you had *in the report* is so stated here, detect and classify; isn't that right, Dr. Patterson?

A: Can't classify without detecting.[294]

* * *

Q: *In your report* is it correct to say that you defined a method of genotyping?

A: Genotyping is, you know, *what we all know it to be and what I practice every day*.

Q: And did you, with respect to genotyping, define it as such; "Genotyping refers to the process of detecting and classifying

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[293] Trial Tr., 8/31/06, v. II, 36:18-25.

[294] Trial Tr., 8/29/06, v. III, 28:19-29:3 (emphasis added).

the different strains of the virus as manifested by nucleotide sequence variation in a certain region of the virus Genome." Is that your definition, sir?

A: Is that taken from my report?

Q: Yes. I don't wish to be unfair here. If you wish to check me on this, look at page four under the category "What is Genotyping"?.

A: *It is what's in the report.*

Q: Thank you. And that's your definition?

A: Yes.

Q: And you also looked at the definition of specifically hybridizes; am I correct?

A: Yes.

Q: … How did you define specific hybridization at the time you wrote that report?

A: As it relates to genotype, it means binding to the genotype that you wish to target and not binding to other genotypes.[295]

* * *

Q: … [I]s it not correct to say that *in that report* you define specifically hybridizes as hybridization with no mismatches?

A: As it's stated, it says, "This element in Claim 1 means using a probe that hybridizes with no mismatches to a nucleotide sequence within the domain that extends between the nucleotides at positions -291 and -66 of the 5' untranslated region of the HCV."

Q: And that was the definition that you wrote *in this report*, correct?

A: *In this report, yes.*[296]

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[295] Trial Tr., 8/29/06, v. III, 31:8-32:8 (emphasis added).

[296] Trial Tr., 8/29/06, v. III, 34:17-35:2 (emphasis added).

Far from establishing that Dr. Patterson's opinions at trial were based on a claim construction that was somehow "erroneous" or differed from the Court, the testimony showed Dr. Patterson's opinion testimony with respect to the invalidating impact of the '718 patent were adapted to, and ultimately remained unchanged in light of, the Court's claim construction. This is, of course, perfectly consistent with Dr. Patterson's qualification in each of his expert reports that "I reserve the right to supplement my conclusions in this report based on additional information that may be discovered during the course of this litigation, including but not limited to the Court's construction of the asserted claims of the patent-in-suit."[297] Thus, Dr. Patterson's testimony at trial supported the invalidating effect of the '718 patent on Innogenetics' patent. Because that testimony was offered in light of the Court's claim construction, the Court's entry of judgment was improper.

Even if Dr. Patterson's testimony at trial had been based on a definition of "method of genotyping" that was limited to "detecting and classifying the different strains of the virus," this would have been consistent with, and not at odds with, the Court's construction of genotyping as "distinguishing and classifying" among types. As Dr. Patterson opined at trial, one "[c]an't classify without detecting."[298] Naturally, one cannot classify or distinguish something before identifying that it exists, a point that the patent examiner made clear during the prosecution of Innogenetics' '704 patent. In her Statement of Reasons for Allowance, the examiner established beyond dispute that genotyping is a *specific type of detection* that allows distinguishing between the genotypes detected:

> [T]he instant methods are concerned with "genotyping" rather than just "detecting" HCV. Although genotyping falls under the

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[297] Patterson Invalidity Expert Report, 4/10/06, Dkt. No. 33, at 1.

[298] Trial Tr., 8/29/06 v. III, 29:3.

> umbrella of detecting, **it is a specific and selective type of detection whereby different genotypes of similar virus strains can be distinguished**. Mere detection methods permit detection of numerous types and subtypes without distinguishing among them. Hence, the term "method of genotyping" means distinguishing among HCV types and/or subtypes.[299]

As the Court construed it, genotyping requires classifying and distinguishing among types of HCV.[300] This is consistent with "a specific and selective type of detecting whereby different genotypes of similar virus strains can be distinguished," as articulated by the examiner, and it is equally consistent with Dr. Patterson's opinion in his report (to which his testimony at trial was not limited) that genotyping refers to detecting and classifying different strains of the virus.

Similarly, the definition of "specifically hybridizing" that Dr. Patterson articulated in his report is not at all incompatible or mutually exclusive with the Court's interpretation of the same term. Whereas the Court interpreted "specifically hybridizing" to mean hybridization of a probe to a target sequence, and not to a non-target sequence, Dr. Patterson defined the term with even more precision in his report. Dr. Patterson interpreted the term to require hybridization with no "mismatches," i.e., with complete complementarity between every nucleotide of a probe and every nucleotide of its target sequence. A probe that binds with no mismatches will, as the specification of the '704 patent teaches, "specifically hybridize." In fact, the '704 patent even warns that so much as "even single mismatches abolish hybridization in this assay."[301]

Thus, as the '704 patent and Dr. Patterson's report make clear, using probes that hybridize with no mismatches is a way to ensure "specific hybridization" between a probe and

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[299] DX 301 at 00821; Gross Decl. Ex. J.

[300] Opinion and Order, 8/11/08, Dkt. No. 218, at 31.

[301] DX 300, '704 patent, Gross Decl., Ex. K, 27:11-14.

only its intended target sequence. Accordingly, the '718 patent taught and disclosed every element of claim 1, as construed by the Court, as well as claims 9, 12 and 13.

C. Dr. Patterson's Effort To Clarify His Opinions On The Cha PCT Application And Resnick '718 Patent In A Supplemental Report Was Appropriate And Not A Rule 26 "Violation"

Ironically, in the same breath it calls for punishment for Abbott for its supposed efforts to "surprise" Innogenetics with undisclosed expert testimony from Dr. Patterson, Innogenetics manages to find fault with Abbott for Dr. Patterson's effort, long before trial, to supplement and clarify the opinions in his original report. But there was nothing wrong with Dr. Patterson's supplemental report. It was a timely effort to clarify, and not rebut, opinions expressed in his original report about two prior art references that were well known by Innogenetics and its expert.

1. Dr. Patterson's Proposed Supplement Addressed Only Prior Art Which He Discussed In His First Report

In his first report, Dr. Patterson wrote about and described "probes taught by Cha [that] specifically hybridize to the 5'-UT region."[302] Included throughout his first report are numerous discussions of Cha's probes "77" and "78," which Dr. Patterson describes at length.[303]

In Dr. Patterson's supplement, he clarified how Cha's probes 77 and 78 apply to the nomenclature and sequence numbering used by Innogenetics in, among others, claims 2, 3, 6

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[302] Patterson Invalidity Expert Report, 4/10/06, Dkt. No. 33, at 12-17.

[303] For just a few examples, *see id.* at 11 ("HCV is genotyped using genotype-specific probes (SEQ IDs 77 and 78) …."); *id.* at 14 ("… Sequence No. 77 (5'-UT) was used to detect Genotype III, Sequence No. 78 (5'-UT) was used to detect Genotype IV.") (quoting the Cha PCT Application); *id.* at 15 (citing Cha's description of SEQ IDs 77 and 78); *id.* at 15 ("[T]he Cha Application SEQ IDs 78 and 120-125 encompass entirely the regions identified in claim 3 ….").

and 7.[304] As Dr. Patterson explained, this exercise was intended "[t]o avoid any confusion about the nucleotide position of these probes using the nomenclature of the '704 patent," which nomenclature varies from the nomenclature and numbering system used in the Cha PCT Application to describe the same nucleotide positions.[305] Every comment in his supplement is consistent with his original statements about the Cha PCT Application in his first report, including his opinion about claim 1, from which all other claims in Innogenetics' patent depend:

> [T]he Cha Application teaches using a probe that specifically hybridizes to the domain extending from the nucleotides at positions -291 to -66 of the 5'-UT region of HCV. … see also Cha [PCT] Application, p. 36 (listing SEQ IDs 77 and 78).[306]

Dr. Patterson's opinion that the Cha PCT Application is an invalidating prior art reference never wavered, nor was it altered by his supplement.

Nothing about the Cha PCT Application could have surprised Innogenetics. The Cha PCT Application has been at issue in this case since the beginning, when Abbott first invoked it by application number in its affirmative defense of patent invalidity.[307] Innogenetics has been dealing with the Cha PCT Application for years, at least as early as 1994, when it was forced to amend its claims in a corresponding European patent application to avoid the teachings

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[304] Dr. Patterson's Supplemental Report also include a clarification and correction with regard to the Kanai reference. (Supplement to Expert Report of Bruce K. Patterson, M.D., Regarding the Invalidity of Innogenetics, N.V.'s U.S. Patent No. 5,846,704, 5/19/06, Dkt. No. 59, (hereinafter, Patterson Supp. Invalidity Report), at 1.) Because that supplementation was allowed, it is not discussed here.

[305] Patterson Supp. Invalidity Report, 5/19/06, Dkt. No. 59, at 1.

[306] Patterson Invalidity Report, 4/10/06, Dkt. No. 33, at 15.

[307] *See* Answer, Affirmative Defenses and Counterclaim of Abbott Laboratories, 10/31/05, Dkt. Nos. 7-8, pp. 3-4.

of the Cha PCT Application, specifically with respect to probes 77 and 78.[308] Innogenetics' claim of surprise because Dr. Patterson supplemented his report regarding the Cha PCT Application's probes 77 and 78, when he already had discussed Cha's use of those probes for genotyping HCV and Innogenetics had known independently of this prior art for years, is simply untenable.

Dr. Patterson also supplemented his report with respect to the '718 patent,[309] another reference that he had described extensively in and included with his first report.[310] In his first report, Dr. Patterson clearly stated his opinion with respect to Innogenetics' claim 1, from which all of the claims in Innogenetics' patent depend: "The '718 patent teaches using oligonucleotide probes hybridizing to domains contained within the nucleotide domain -291 to -66 of the 5'-UT region of HCV."[311] Referring to a table of probe sequences numbered 1-14 in the '718 patent, Dr. Patterson described the use of probes targeting a specific region to classify and detect different types of HCV, discussing as an example a probe called SEQ ID NO. 8.[312]

In his supplement, Dr. Patterson clarified that other probes from the same Table 1 in the '718 patent, specifically SEQ ID NO. 9, were used in the same fashion.[313] Dr. Patterson explained how the '718 patent's probes 8 and 9 apply to the nomenclature and sequence

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[308] *See* Declaration of Devanand J. Crease, 5/15/06, Dkt. Nos. 56-57, Exh. A (European File Wrapper) at AB17944-45, AB17846, AB17852-53.

[309] *See* Patterson Supp. Invalidity Report, 5/19/06, Dkt. No. 59, at 2.

[310] *See* Patterson Invalidity Expert Report, 4/10/06, Dkt. 33, at 19-21, 23-31.

[311] *Id.* at 19.

[312] *Id.* at 19-20 ("For example, probe sequence identification number 8 binds to the nucleotide domain -244 to -221.") (citing Table 1 of the '718 patent).

[313] *See* Patterson Supp. Invalidity Report, 5/19/06, Dkt. No. 59, at 2-3.

numbering used by Innogenetics' '704 patent, including as they are used in claims 1-3 and 9.[314] Every comment in his supplement was consistent with and reinforced Dr. Patterson's opinion in his first report, namely, that "[t]he '718 patent teaches using oligonucleotides probes hybridizing to domains contained within the nucleotide domain -291 to -66 of the 5'-UT region of HCV."[315] Dr. Patterson's opinion remains that the '718 patent is an invalidating prior art reference to Innogenetics' '704 patent.

2. Dr. Patterson's Proposed Supplement Complied With The Court's Preliminary Pretrial Conference Order, Which Contemplated Such Limited Supplementation

The Court's order established clear rules for supplemental expert reports: (1) there shall be no rebuttal reports, (2) supplementation is limited to matters raised in an expert's first report, (3) it must be in writing, and (4) it be served no later than five days before the expert's deposition.[316] Dr. Patterson's supplement met these criteria.

With respect to the first two requirements, *none* of Dr. Patterson's supplement was rebuttal material, as it was appropriately limited to his first report. Innogenetics' expert's report addressed some of the same topics as Dr. Patterson's supplement, but this did not make it rebuttal testimony; it just showed that both parties retained experts to opine on the prior art. Dr. Patterson's supplement did not endeavor to rebut Dr. Worman's work and was specifically "limited to matters raised in an expert's first report," namely, two prior art references Dr. Patterson already had discussed at length.

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314 *Id.*

315 Patterson Invalidity Expert Report, 4/10/06, Dkt. 33, at 19.

316 *See* Preliminary Pretrial Conference Order, 11/25/05, Dkt. No. 12, at 2.

It was also exactly the kind of report that is encouraged by Rule 26 itself, which imposes a duty on a party to "supplement at appropriate intervals its [Rule 26] disclosures (a) if the party learns that in some material respect the information disclosed is incomplete or incorrect and if the additional or corrective information has not otherwise been made known to the other parties during the discovery process or in writing."[317] Here there was no nefarious plot; on the contrary, Abbott realized it had a duty to disclose information that would make Dr. Patterson's report more complete, and it tried to do so pursuant to Rule 26. Attempting to complete one's pretrial disclosures so the other side can be adequately prepared for trial is something that should be encouraged, not discouraged.

Dr. Patterson's report also complied with the last two criteria, as it was provided in writing on May 19, 2006, more than eight weeks before Dr. Patterson's second deposition. In sum, Dr. Patterson's short supplement, regarding prior art already addressed in his first report and provided in writing well in advance of his deposition, was an appropriate supplementation contemplated by the Court's order and offered at a point in the litigation that eliminated any potential unfair surprise or prejudice to Innogenetics. That Innogenetics tried to strike it under these circumstances only shows its recognition that Dr. Patterson's opinions were dangerous for its case. Though Innogenetics had argued for striking the supplement on the basis that it would suffer prejudice if it were allowed, it had the opportunity to thoroughly depose Dr. Patterson on all of his invalidity contentions on July 27. But consistent with its pattern of avoiding meaningful deposition questions and then later arguing to block witnesses' testimony on the basis that they did not provide testimony on the subject before trial, Innogenetics did not thoroughly depose Dr. Patterson on invalidity issues when it had the opportunity. In any case, to grant

[317] Fed. R. Civ. P. 26(e)(1) (West 2006).

enhancement and award attorneys' fees on the basis of a party's good faith effort to supplement, and provide more information to its opponent, well before trial, would run directly contrary to the purposes of, and duties imposed by, Rule 26.

D. Dr. Patterson and Others Were Poised To Provide Compelling Evidence of The Obviousness Of The '704 Patent, Until They Were Completely Blocked From Doing So On The Purported Basis That Dr. Patterson's Report Did Not Include Disclosure Of Expert Opinions On Motivation To Combine

1. *Innogenetics'* Argument That Abbott "Dropped" Its Obviousness Defense Is A Striking Example of Innogenetics' Litigation Misconduct

Innogenetics finds litigation misconduct wherever it looks - except for its own doorstep. It perpetuates "facts" it knows to be false all throughout its brief but this is a particularly stellar example:

> The Court then ruled that Dr. Patterson would not be permitted to testify on the issue of obviousness because he had failed to adequately disclose any opinion relating to obviousness under Fed. R. Civ. P. 26(c)(1). [citation omitted] Only after that determination did Abbott finally drop its obviousness claim, and even then it did so just three days prior to trial commencing.[318]

First, as discussed in more detail below, the Court did not just exclude Dr. Patterson's testimony on obviousness; it excluded the testimony of *all* witnesses on the subject of obviousness. The record is crystal clear on the Court's ruling:

> Motion to exclude the testimony of Dr. Patterson or any other witness on issue of obviousness. GRANTED[319]

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[318] Motion, at 24-25.

[319] *See* Pretrial Order, 8/18/06, Dkt. 256, at 3. Also, the reason for excluding the evidence was not, as Innogenetics states, because he had purportedly failed to disclose *any* opinion relating to obviousness; it was because he had purportedly failed to disclose his opinion on motivation to combine. As set forth above, Dr. Patterson's disclosures on motivation to combine and on obviousness generally were more than adequate under Rule 26.

Of course, this ruling obliterated Abbott's obviousness defense since one cannot pursue a defense if one is not allowed any witnesses on the subject. And at trial, Innogenetics' counsel falsely suggested that Abbott was "dropping" its defense but Abbott countered:

The Court:	. . . I do think it is important to know whether you're going to pursue your obviousness claim as part of your validity defense.
[Def's Counsel]:	Your Honor, we read the Court's ruling excluding any testimony from any witness on obviousness to limit our options in that regard and in light of that ruling, we intend certainly to honor it. Abbott would like to preserve its objection --
The Court:	Of course.
[Def's Counsel]:	-- in that regard, but we intend to following [sic] the Court's ruling, and in fact, we did send a letter to plaintiff's counsel advising them that we did intend to honor that ruling.
The Court:	Okay.
[Pltf's Counsel]:	*And I understand that means they're abandoning the defense for purposes of the case.*
The Court:	For the trial at least.
[Pltf's Counsel]:	Yes.
[Def's Counsel]:	*We're not waiving anything, we're not abandoning anything.*[320]

Here the facts show that Abbott was barred, right before trial and over its objection, from putting on its obviousness case. Innogenetics' statement about Abbott "dropping" the claim is a fabrication meant to create the false impression that Abbott believed its obviousness defense was weak but pushed it nonetheless and then voluntarily waived it just before trial, inconveniencing the Court and Innogenetics. It is ironic that Innogenetics would use such lies to support a finding of exceptional case based on Abbott's supposed litigation

[320] Trial Tr. 8/28/06, 9:6-25.

misconduct. And, this is not the only example. Innogenetics' counsel has submitted with a declaration two documents it calls a "timeline/continuum." Innogenetics' counsel attempts to pass them off as fact,[321] but they are argument at best and in many cases actually affirmative misstatements of the facts. Abbott has corrected the record by including in support of this motion a response to the timelines/continuua that includes the true facts.[322] Abbott has also tried to identify and correct Innogenetics' many misstatements throughout this brief.

Innogenetics apparently feels it must misrepresent the facts because the actual facts do not support a claim for enhancement or attorneys' fees. But in fairness, this Court must ignore Innogenetics' creative arguments, go beyond its own rulings, and look at the underlying factual record to determine whether Abbott had good faith arguments to support its case. That exercise compels a result in favor of Abbott.

2. Dr. Patterson Was To Present Testimony On Motivation To Combine and Other Facts and Opinions Pertinent To Obviousness

Innogenetics finds fault with Abbott for supposedly having no support for its obviousness defense. As seen above, Innogenetics ignores the anticipatory prior art references that were available, as well as the evidence on the state of the art in the field at the relevant timeframe, both of which are highly relevant to obviousness. It also ignores the fact that Abbott had prepared a great deal of testimony that was specifically relevant to obviousness, but that was completely blocked by the Court in a last-minute ban on the subject.

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[321] Declaration of Lissa R. Koop, at ¶¶ 2-3. Innogenetics also improperly suggests in its brief that these timelines are not argument or demonstratives, but fact. *See* Motion, at 5-6 ("Exhibit A . . . is a timeline/continuum annotating Abbott's willful infringement to the trial record. . . . Exhibit B . . . is a timeline/continuum of Abbott's litigation misconduct").

[322] *See* Abbott's Response To Both Of Innogenetics' Timelines (Exhibits A and B of the Koop Declaration), Gross Decl., Ex. A.

A review of Dr. Patterson's expert report shows that he was prepared to testify as to extensive facts and opinions concerning the subject of "motivation to combine" on which the Court based its ruling. First, Dr. Patterson addressed the level of skill in the prior art, beginning with an explanation of his own history as a scientist in the relevant time period (and since), including his work overseeing more than 5000 HCV quantification assays and over 1500 HCV genotype assays, including realtime PCR.[323] Dr. Patterson then articulated the level of ordinary skill in the art at the time of the claimed invention.[324] Next, Dr. Patterson addressed the prior art, explaining its scope, content, and how (if at all) it differed from the claimed invention. Dr. Patterson began with a general description of the field, including those basic techniques claimed in the '704 patent, which had been successfully used in the laboratory for years (*e.g.*, hybridization and detection methods).[325]

In his report, Dr. Patterson then continued to discuss the scope of a particular prior art reference Abbott was asserting as prior art under sections 102 and 103, the Cha PCT Application, and its overwhelming similarity to the claimed invention.[326] Then Dr. Patterson turned to the other prior art references considered in his obviousness opinion and described in detail their contributions to the field of HCV genotyping.[327]

What was clear from this discussion about the various contributions to the field of HCV genotyping is that the differences, if any exist, between the prior art and the claimed invention are minimal. Because Dr. Patterson opined that a number of these references, *e.g.*, the

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[323] Patterson Invalidity Expert Report, 4/10/06, Dkt. 33, at 1-2.

[324] *Id.*, at 2.

[325] *Id.*, at 3-4.

[326] *Id.*, at 9-14.

[327] *Id.*, at 21-23.

1992 Cha Article, the Cha PCT Application, the '718 patent and the Lee Article all describe *probe-based hybridization methods of genotyping HCV using the 5' UTR*, there remained little, if anything, to say about any alleged "differences" between these references and the prior art.[328] With respect to other references that did not describe probe-based methods, the differences between them and the claimed invention are facially apparent. [329]

As for the "motivation to combine" in particular, Dr. Patterson's report thoroughly explained why one skilled in the art, apprised of the HCV literature in the field around 1992, would rely on the combinations of the work published by other scientists that he disclosed in his report. [330] In addition, Dr. Patterson opined in the report that some references on their own, such as the Cha PCT Application, provided sufficient motivation to combine.[331]

Despite all this, the Court ruled that it was "not going to allow Dr. Patterson's testimony on the issue of obviousness,"[332] and officially excluded it in its pretrial order dated August 21, 2006.[333] The Court appeared to base this decision on its view that Dr. Patterson had

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[328] *See, e.g., id.*, pp. 22-23.

[329] *Id.*, at 21-22 (describing Choo et al. and Kato et al. teaching "sequencing of the prototypic genome," and Kanai et al. teaching genotype-specific responses to therapies).

[330] *Id.*, at 23-32.

[331] Pretrial Conf. Tr., 8/17/06, Dkt. No. 260, 18:7-13. Where, as here, a single prior art reference, like the Cha PCT Application, contains elements which render a patent claim obvious to one of ordinary skill in the art, there is no need to combine references at all. *See* 35 U.S.C. § 103; *see also B.F. Goodrich Co. v. Aircraft Braking Sys. Corp.*, 72 F.3d 1577, 1582 (Fed. Cir. 1996); *In re O'Farrell*, 853 F.2d 894, 902 (Fed. Cir. 1988); *SIBIA Neurosciences, Inc. v. Cadus Pharmaceutical Corp.*, 225 F. 3d 1349, 1356 (Fed. Cir. 2000). For this additional reason, the Court's decision to block all testimony as to obviousness was unfounded.

[332] Pretrial Conf. Tr., 8/17/06, Dkt. No. 260, 18:17-22.

[333] *See* Pretrial Order, 8/18/06, Dkt. No. 256, at 3 (COURT: "Motion to exclude the testimony of Dr. Patterson or any other witness on issue of obviousness. GRANTED").

failed to include in his expert report sufficient disclosure on the element of motivation to combine.[334]

That Dr. Patterson's testimony was excluded was not Abbott's fault. There was nothing wrong with Dr. Patterson's disclosure and with respect to the issue of motivation to combine, the report was perfectly in line with Federal Circuit law on the subject. As the Federal Circuit explained in *Alza Corp. v. Mylan Labs.* just last month, "We do not have a rigid test that requires an actual teaching to combine before concluding that one of ordinary skill in the art would know to combine references." *Alza*, -- F.3d --, No. 06-1019, 2006 WL 2556356, at *4 (Fed. Cir. Sept. 6, 2006) (emphasis in original). Instead, "the teaching, motivation, or suggestion may be implicit from the prior art as a whole, rather than expressly stated in the references…. The test for an implicit showing is what the combined teachings, knowledge of one of ordinary skill in the art, and the nature of the problem to be solved as a whole would have suggested to those of ordinary skill in the art." *Id.* at *3 (*quoting In re Kahn*, 441 F.3d 977, 987-88 (Fed. Cir. 2006) (*citing In re Kotzab*, 217 F.3d 1365, 1370 (Fed Cir. 2000)). "At its core," said the *Alza* Court, "our anti-hindsight jurisprudence is a test that rests on the unremarkable premise that legal determinations of obviousness, as with such determinations generally, should be based on evidence rather than on mere speculation or conjecture." *Id.* at *3. Accordingly, "rejections on obviousness grounds cannot be sustained by mere conclusory statements" but "there must be ***some*** articulated reasoning with ***some*** rational underpinning to support the legal conclusion of obviousness." *Id.* at *3 (*quoting In re Kahn*, 441 F.3d at 987-88) (emphases added in *Alza*).

[334] Pretrial Conf. Tr., 8/17/06, Dkt. No. 260, 15:11-15 ("So then when I read the obviousness, it was just sort of well, if you don't find anticipation, you could combine some things. But it was never made clear to me what things you would combine").

Just one week ago, in *Dystar Textilfarben GmbH & Co. Deutschland KG v. C.H. Patrick Co. and Bann Quimica Ltda.,* the Federal Circuit again went out of its way to clarify its view on the "suggestion test. " "In contrast to the characterization of some commentators, the suggestion test is not a rigid categorical rule. The motivation need not be found in the references sought to be combined, but may be found in any number of sources, including common knowledge, the prior art as a whole, or the nature of the problem itself." *Dystar*, -- F.3d --, No. 06-1088, 2006 WL 2806466, at *4 (Fed. Cir. Oct. 3, 2006). The Court condemned the kind of approach taken by this Court:

> Dystar's argument misreads this court's cases and misdescribes our suggestion test, echoing notions put forth recently by various commentators and accepted in major reports. A 2003 report by the Federal Trade Commission, for example, quoted testimony of certain witnesses that this court requires 'specific and definitive [prior] art references with clear motivation of how to combine those references' and requires the PTO to find 'the glue expressly leading you all the way [to obviousness]' and 'connect the dots . . . very, very clearly.'

Id. at *8. The Federal Circuit noted that commentators seeking to give the "suggestion test" rigidity had misquoted statements from *In re Dembiczak,* 175 F.3d 994 (Fed. Cir. 1999), *In re Lee*, 277 F.3d 1338 (Fed. Cir. 2002), and *Ruiz v. A.B. Chance Co.*, 234 F.3d 654 (Fed. Cir. 2000) and that "each of the above-cited cases correctly applies the suggestion test and *by no means requires an explicit teaching to combine to be found in a particular prior art reference." Id.* at *9 (emphasis added).

Moreover, Dr. Patterson's report contained "a complete statement" of his opinions on motivation to combine "and the basis and reasons therefor," as required by Fed. R. Civ. P. 26(a)(2)(B). In the Seventh Circuit, "[a] complete report must include the substance of the testimony which an expert is expected to give on direct examination together with the reasons

therefor." *Salgado v. General Motors Corp.*, 150 F.3d 735, 742 n.6 (7th Cir. 1998). It does not require that the report contain the verbatim testimony to be used at trial. "Rule 26(a)(2)(B) . . . does not require that a report recite each minute fact or piece of scientific information that might be elicited on direct examination . . . ." *McCoy v. Whirlpool Corp.*, 214 F.R.D. 646, 652 (D. Kan. 2003). Dr. Patterson's report was appropriately "written in a manner that reflects the testimony to be given by the witness. . . ." Fed. R. Civ. P. 26, advisory committee's note to 1992 amendments; *see also Salgado*, 150 F.3d at 742 n.6.

The Court's view -- that a sufficient disclosure must have explicit details of a specific suggestion or motivation to combine[335] -- is not the law and in fact has been expressly rejected by the Federal Circuit. Dr. Patterson's report was more than appropriate and Abbott should have been allowed to present his testimony on obviousness.

3. Other Witnesses Had Relevant Testimony To Share On Motivation to Combine

As the Federal Circuit explained last week in *DyStar*, the suggestion test "not only permits, but *requires* consideration of common knowledge and common sense." *Id.* at *11 (emphasis in original) (citing *In re Kotzab*, 217 F.3d 1365, 1369 (Fed. Cir. 2000) ("A critical step in analyzing the patentability of claims pursuant to section 103(a) is casting the mind back to the time of invention, to consider the thinking of one of ordinary skill in the art, guided only by the prior art references and the then-accepted wisdom in the field"); *Motorola, Inc. v. Interdigital Tech. Corp.*, 121 F.3d 1461, 1472 (Fed. Cir. 1999) ("[T]he suggestion to combine may come from the prior art, as filtered through the knowledge of one skilled in the art"); *In re Bozek*, 416 F.2d 1385, 1390 (C.C.P.A. 1969) ("Having established that this knowledge was in the art, the

[335] Pretrial Conf. Tr., 8/17/06, Dkt. No. 260, 17:12-22.

examiner could then properly rely . . . on a conclusion of obviousness 'from common knowledge and common sense of the person of ordinary skill in the art without any specific hint or suggestion in a particular reference")).

Thus, motivation to combine is "inextricably linked to the level of ordinary skill." *DyStar*, 2006 WL 2806466, at *13. And contrary to this Court's apparent belief, there is no requirement that a party submit expert testimony on the subject of motivation to combine. A motivation to combine can be established in numerous ways: through prior art or non-prior art documents reflecting the knowledge of persons of ordinary (or even less than ordinary) skill in the art in the relevant timeframe, through lay witness testimony, and through the testimony of prior art inventors.

For example, in *National Steel Car, Ltd. v. Canadian Pacific Railway, Ltd.*, 357 F.3d 1319 (Fed. Cir. 2004), the Court relied on two pieces of evidence to establish a motivation to combine, neither of which was prior art. The first reference was a drawing prepared by an engineer; the second was a statement by a marketing person. Neither the engineer nor the marketing person met the court's definition of "one of ordinary skill in the art," but the Federal Circuit found it error to discount this evidence, reasoning that something that has been rendered obvious to a relative newcomer in a field is probative of what would be obvious to someone who has been around for a longer period of time. *Id.* at 1338. "It has long been the law that the motivation to combine need not be found in prior art references, but equally can be found 'in the knowledge generally available to one of ordinary skill in the art.'" *Id.* at 1337 (*quoting In re Jones*, 958 F.2d 347, 351 (Fed. Cir. 1992) (*citing In re Fine*, 837 F.2d 1071, 1074 (Fed. Cir. 1998)). *See also NPF v. Smart Parts*, No. 05-1273, 2006 WL 1876659, at *6 (Fed. Cir. June 27, 2006) (unpublished slip copy) (affirming the district court's determination that testimony from

non-expert, third party electronics designers was sufficient to establish a motivation to combine); *Rogers v. Desa*, No. 02-1247, 2006 WL 1965660, at *5-6 (Fed. Cir. July 13, 2006) (unpublished slip copy) (affirming finding of obviousness where motivation to combine was established by evidence that third party developers of ordinary skill in the art had considered the alleged combination); *Neupak, Inc. v. Ideal Mfg.*, 41 Fed. Appx. 435, at **4 (Fed. Cir. 2002) (unpublished) ("Although Ideal correctly notes that obviousness is determined from the perspective of a hypothetical person of ordinary skill in the art, the district court did not err by considering the inventors' testimony in the course of reaching its decision. The inventors' testimony was relevant to whether the inventions would have been obvious to a person of ordinary skill in the art, and there is no indication that the trial court misunderstood the proper legal standard or gave the inventors' testimony undue weight"); *Cross Medical Products, Inc.* v. *Medtronic Sofamor Danek, Inc.*, 424 F.3d 1293, 1322 (Fed. Cir. 2005) (evidence that clinical investigators recognized the problem could serve as a motivation to combine: "Evidence that a person of ordinary skill in the art recognized the same problem to be solved as the inventor and suggested a solution is, at the least, probative of a person of ordinary skill in the art's willingness to search the prior art in the same field for a suggestion on how to solve that problem." *citing Pro-Mold & Tool Co. v. Great Lake Plastics, Inc.*, 75 F.3d 1568, 1573 (Fed. Cir. 1996)).

Thus, motivation to combine could have been established through the testimony of the prior art inventor Dr. Cha[336] who, as Innogenetics admitted, was familiar with the knowledge that persons of ordinary skill in the art would have had at the relevant time.[337]

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[336] Motion in Limine Re Cha and White, 8/10/06, Dkt. No. 190, at 1, 2; Oppo. to Motion In Limine Re Cha and White, 8/16/06 Dkt. No. 241, at 1.

[337] Trial Tr., 8/29/06, v. I, 66:7-11 ("Now we are at trial and Dr. Cha is going to march through all of his knowledge and experience in front of the jury which goes to the heart of (footnote continued)

Motivation to combine also could have been established through other fact witnesses that had such information, like Dr. Leckie[338] or Dr. White,[339] or through cross-examination of Dr. Worman[340] or inventor of the patent-in-suit Dr. Maertens,[341] both of whom testified and made important admissions as to the state of the art in 1992. Motivation also could have been established based on the prior art references alone. *Alza*, 2006 WL 2556356, at *7-8.

4. Dr. Patterson and Other Abbott Witnesses Had Testimony On Obviousness Beyond That Relevant To Motivation To Combine, But It Was Also Improperly Banned By The Court

Also stemming from the Court's erroneous view that Abbott was required to present expert testimony on motivation to combine and had not properly prepared to do so was its decision to block all testimony on the subject of obviousness by any other Abbott witness besides Dr. Patterson.[342]

Of course, the underpinnings of the obviousness determination are all questions of fact, and lay witnesses are entitled to testify to facts supporting obviousness without having to provide a written report. Fed. R. Evid. 701; Fed. R. Civ. P. 26(a)(2)(B) (only the testimony of a witness who is retained or specially employed to provide expert testimony in the case, or whose duties as an employee of the party regularly involve giving expert testimony, must "be accompanied by a written report prepared and signed by the witness"). *Accord, Union Pacific*

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enablement which their expert didn't opine on. It is what one of ordinary skill in the art would understand").

338 *See, e.g.*, Trial Tr., 8/29/06, v. I, 37:1-51:23.

339 Pretrial Conf. Tr., 8/17/06, at 35:13-37:16.

340 *See, e.g.*, Trial Tr., 8/30/06, v. I, 38:2-39:11(discussing knowledge of people skilled in the art in 1992); 48:11-20; v. II, 49:13-20; 50:1-10; 56:11-18.

341 *See, e.g.*, Trial Tr., 8/30/06, v. III, 23:23-31:18.

Resources Co. v. Chesapeake Energy Corp., 236 F.3d 684, 693 (Fed. Cir. 2001) (holding eight lay opinion witnesses were properly permitted to provide testimony as to invalidity of the patent-in-suit because they had sufficient personal experience regarding what was known in the industry and prior art in the field at the relevant time).

As with motivation to combine, the testimony of prior art inventors or authors, of persons of ordinary skill in the art and of persons of less than ordinary skill in the art can be highly relevant to the determination of obviousness. Indeed, the testimony of prior art authors is highly relevant, useful and commonly admitted on the issue of obviousness. *See Gambro Lundia AB v. Baxter Healthcare Corp.*, 110 F.3d 1573 (Fed. Cir. 1997); *see also Monarch Knitting Mach. Corp. v. Sulzer Morat GMBH*, 1998 WL 338106 (S.D.N.Y. June 25, 1998). *In re Omeprazole Patent Litig.*, 2002 WL 287785 at *6, n.7 (S.D.N.Y. Feb. 27, 2002); *Eli Lilly & Co. v. Teva Pharm. USA, Inc.*, 2004 WL 1724632 (S.D. Ind. July 29, 2004); *Ajinomoto Co., Inc. v. Archer-Daniels Midland Co.*, 1998 WL 151411 (D. Del. Mar. 13, 1998); *Semi Conductor Energy Laboratory v. Samsung Electronics Co., Ltd.*, 4 F. Supp. 2d 477 (E.D. Va. 1998).

Here, obviousness could have been established through the testimony of the several other fact witnesses noted above. Innogenetics' contention that Abbott had no evidence to support its defenses is demonstrably false, and Innogenetics' request for enhancement and attorneys' fees on this false basis should be denied.

[342] *See* Pretrial Order, 8/18/06, Dkt. No. 256, at 3 ("Motion to exclude the testimony of Dr. Patterson or any other witness on issue of obviousness. GRANTED").

V. DR. MAERTENS' ADMISSION AT TRIAL THAT THE '704 PATENT'S USE OF PROBES 77 AND 78 IN THE 5' UTR TO SPECIFICALLY HYBRIDIZE WAS FIRST INVENTED BY CHA, CONTRARY TO HIS STATEMENT TO THE PTO THAT IT WAS A PART OF HIS INVENTION, SUPPORTS ABBOTT'S VIEW THAT THE '704 PATENT IS UNENFORCEABLE DUE TO INEQUITABLE CONDUCT

Innogenetics seeks one more bite at the apple on inequitable conduct in its latest brief. Since Abbott has twice briefed most of the facts and arguments it believes supports a finding of unenforceability due to inequitable conduct, it incorporates these facts and arguments by reference rather than reproducing them in full here.

What Innogenetics fails to mention in its brief is that *Dr. Maertens actually admitted on the stand at trial that he and his co-inventors made a material misstatement to the PTO*. Maertens et al. claimed in their '704 patent use of the genotype-specific sequences in the 5'UTR, including sequence ID No. 13.[343] This supposed discovery was part of the only independent claim in the '704 patent, claim 1: "specifically hybridizing a probe to a domain extending from minus 291 to minus 66 of the 5' UTR region of hepatitis C."[344]

First, Innogenetics stipulated during trial that the Cha PCT Application disclosed the '704 patent's Sequence ID 13: "Innogenetics does not dispute that Sequence AATCGCTGGGGTGACC is Sequence ID 78 in the Cha application, Cha PCT application, and Sequence No. 13 in the '704 patent."[345] Then, Dr. Maertens admitted that Innogenetics was not

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[343] DX. 300, '704 Patent, Gross Decl., Ex. K, col. 39 (Table 4).

[344] Trial Tr., 8/29/06, v. II, 52:19-23.

[345] Trial Tr., 8/29/06, v. II, 18:1-3.

the first to identify sequence 13 as a genotype-specific sequence and that he and his co-inventors had in fact made no such invention.[346]

"Inequitable conduct occurs when a patentee breaches his or her duty to the PTO of 'candor, good faith, and honesty.'" *Molins PLC v. Textron, Inc.*, 48 F.3d 1172, 1178 (Fed. Cir. 1995). The duty of candor extends to the patentee as well as his representatives. *Id.* at 1178 n.6; *see also* 37 C.F.R. § 1.56(c). A patentee, or its representative, can breach this duty in several ways: "affirmative misrepresentation of a material fact, failure to disclose material information, or submission of false material information." *Id.* A breach of the duty of candor, coupled with intent to mislead the PTO, renders a patent unenforceable. *Id.* Materiality and intent must be shown by clear and convincing evidence. *See Bristol-Myers Squibb Co. v. Rhone-Poulenc Rorer, Inc.*, 326 F.3d 1226, 1233, 34 (Fed. Cir. 2003).

Information is material to patentability when:

> [I]t is not cumulative to information already of record or being made of record in the application, and
>
> (1) It establishes, by itself or in combination with other information, a prima facie case of unpatentability of a claim, or
>
> (2) It refutes, or is inconsistent with a position the applicant takes in:
>
> (i) Opposing an argument of unpatentability relied on by the Office; or
>
> (ii) Asserting an argument of patentability.

37 C.F.R. § 1.56(b) (2004). Once materiality and intent have been shown, the court then must "weigh them to determine whether the equities warrant a conclusion that inequitable conduct has occurred." *Id.* at 1234; *see also Hoffman-LaRoche v. Promega Corp.*,

[346] Trial Tr. 8/30/06, v. III, 60:2-18.

323 F.3d 1354, 1360 (Fed. Cir. 2003) (same). "[W]hen balanced against high materiality, the showing of intent can be proportionally less." *Bristol-Myers Squibb*, 326 F.3d at 1234.

Here, the inventors told the Patent Office that they had invented something that Cha had previously invented; indeed, it is hard to imagine how much more material a misrepresentation could get. Also, the information the inventors concealed, that Cha had in fact invented the use of the genotype-specific sequences in the 5'UTR, including sequence ID No. 13, would have established a prima facie case of unpatentability of claim 1, and thus all of the claims of the '704 patent. This information would have also refuted, and certainly was inconsistent with, the position the applicants took that their invention was patentable.

There were also plenty of facts to establish an intent to deceive. On November 26, 1993, one of the named inventors of the '704 patent, Dr. Maertens, had filed European application No. 94901891.5 (the EP '342 application) in the European Patent Office.[347] As this Court has noted, the claims of this application were "similar," but not identical, to the claims of the '568 application.[348]

The International Searching Authority issued an International Search Report on June 2, 1994, that listed the Cha PCT application as a prior art reference. According to the report, the Cha PCT application was an "X" document – meaning that in light of it, "the claimed invention cannot be considered novel or cannot be considered to involve an inventive step."[349]

In August 1995, the EPO rejected, in light of the Cha PCT application, and on the same basis as the International Search Report, the claims of the EP '342 application. In

[347] Opinion and Order, 7/17/06, Dkt. No. 131, at 3.

[348] Opinion and Order, 7/17/06, Dkt. No. 131, at 3.

[349] Opinion and Order, 7/17/06, Dkt. No. 131, at 4.

December 1995, Innogenetics filed a response to this rejection that amended claim 1 and included the following disclaimer:

> [A] disclaimer has been built into claim 1 to exclude a set of probes which is identical to oligonucleotides with sequence number 77 and 78 as disclosed [in the Cha PCT application]. Applicant wishes to disclaim these two probes out of extreme caution in that they might be considered as reading on present claim 1, i.e. in the event these two probes might (this point is still unclear) function as a set of probes as defined in claim 1.[350]

On August 2, 1996, plaintiff tried to back off of its admission, filing a response to the EPO's second Examination report that amended claim 1 back to its original language and now argued that the Cha PCT application was non-enabling.[351] Plaintiff's new position regarding the Cha PCT was:

> [The Cha application] related to nucleic acid and peptide sequences corresponding to HCV viral genomes which are different from HCV-1. One of the different embodiments set out in D1 are [sic] methods of detecting one or more genotypes of HCV . . . . . Only sequence 77 (Genotype-III) and sequence number 78 (Genotype-IV) were divided from the 5'UR region. . . . [The Cha PCT application] does not teach or suggest in any way that the 5'UR "per se" is, or even might be, a useful target region for deriving genotype specific probes for use in a quick and easy genotyping method for HCV. On the contrary, . . . the presence of Genotypes I and II had to be established using nucleic acids with sequence numbers 73 and 74 which are derived from the envelope region.[352]

The EPO was not fooled. The next Examination Report issued, dated December 11, 1996, stated:

> The Applicants cannot deny the fact that Seq. No. 77 and Seq. No. 78 of the [Cha PCT Application], overlap respectively with the

[350] Opinion and Order, 7/17/06, Dkt. No. 131, at 5-6.

[351] Opinion and Order, 7/17/06, Dkt. No. 131, at 7.

[352] Opinion and Order, 7/17/06, Dkt. No. 131, at 7.

> regions -141 to -117 and -170 to -155 which represent the relative positions in the 5' UR nucleotide sequence of the two variable regions corresponding to probes hereby used for typing of the four different HCV groups (cf. Figure 2 and page 29, lines 13-29). Likewise, it cannot be denied that, e.g., Genotype I as identified by present Probes 5 or 6 seemingly correspond to Genotype IV detected/identified in [the Cha application] by Seq. No. 78.[353]

Interestingly, the EPO also noted that contrary to the applicant's position, the Cha PCT application was an enabling disclosure because "hybridization assays [were] well established techniques in the art."[354]

In April 1997, the plaintiff then amended claim 1 again to "disclaim the teachings of [the Cha application]."[355] In September 1997, the European Patent Office required the same disclaimer for claim 2 and finally granted the '342 patent application with a disclaimer of the two probes (sequences 77 and 78) disclosed in the Cha PCT application's genotyping analysis.[356]

Meanwhile, back in the U.S., the '568 application claiming the use of the genotype-specific sequences in the 5'UTR, including sequence ID No. 13 (the same as sequence 78),[357] was filed on July 18, 1994.[358] When it was filed, included with it was the same International Search Report that was before the European Patent Office.[359]

Despite the report's determination that the Cha PCT application was an "X" document, the applicants' counsel, Mr. Muserlian, felt comfortable in telling the PTO that the

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[353] Opinion and Order, 7/17/06, Dkt. No. 131, at 8.

[354] Declaration of Devanand J. Crease, Dkt. Nos. 56-57, Exh. A (European File Wrapper) at AB17890.

[355] Opinion and Order, 7/17/06, Dkt. No. 131, at 9.

[356] Opinion and Order, 7/17/06, Dkt. No. 131, at 9-10.

[357] DX 301, Gross Decl., Ex. J.

[358] DX 300, '704 Patent, Gross Decl., Ex. K, at 1.

[359] Opinion and Order, 7/17/06, Dkt. No. 131, at 4.

Cha PCT Application "do[es] not relate to the invention."[360] He says now that he had done no independent investigation concerning the relevance of the reference, but especially in light of the International Search Authority's view, even that information itself (that he had done no investigation) would have arguably been material to the PTO examiner in fully understanding his statement that it was unrelated (or the fact that he had no basis for such a statement).

By the end of 1995, there is absolutely no question that Innogenetics and/or its counsel knew that the Cha PCT contained the subject matter it was claiming as its own.[361] By this time, the European Patent Office had issued its first rejection of the EP '342 on the basis of that particular aspect of the Cha PCT Application, and Innogenetics had responded in December 1995 with its specific disclaimer of this same subject matter.[362] And Dr. Maertens certainly understood the Cha PCT reference and its significance.[363] He testified at deposition that he was the "chief or primary technical contact within Innogenetics" for Ann DeClerq and other patent agents involved in the European prosecution, and filled the same role in the U.S. prosecution.[364]

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[360] Opinion and Order, 7/17/06, Dkt. No. 131, at 4.

[361] Opinion and Order, 7/17/06, Dkt. No. 131, at 5-6.

[362] Opinion and Order, 7/17/06, Dkt. No. 131, at 5-6.

[363] Dr. Maertens' deposition was good reason to question his credibility. For example, he did not testify credibly at his deposition about the Cha reference or the European Patent Office's view on it. Deposition of Geert Maertens, 2/15/06, Dkt. No. 86, 179:13-25 (Q. "Do you agree with the characterization of the Cha PCT application as an X reference? [objection omitted]. "A. I'm not entirely familiar with the meaning of an X document and all its aspects that a patent attorney would understand, but I think, a document of particular relevance, the claimed invention cannot be considered novel or considered to involve an inventive step when the document is taken alone. I think we have always taken the stance that this should not be considered to be an X document. And finally, also the European examiner agreed with that point of view." Q. "Isn't it the case, though, that the claim 1 of the European patent that eventually issued out of the European Patent Office has a disclaimer?" A. "That's correct").

[364] Maertens Depo., 2/15/06, Dkt. No. 86, 111:5-113:16; 114:5-16.

Yet neither Mr. Muserlian, Dr. Maertens, nor Innogenetics said anything to the U.S. Patent Office.

Perhaps that was because Innogenetics was busy manufacturing a new strategy to deal with the Cha PCT Application, amending claim 1 back to its original language and arguing non-enablement.[365] But Innogenetics was put on notice again during the pendency of the U.S. '568 application, when the European Patent Office argued that sequences 77 and 78 were in the Cha PCT application[366] in April 1997 and Innogenetics was forced to amend the '342 application's claims 1 and 2 again to "disclaim the teachings of [the Cha application]" in September 1997.[367] Only as a condition of that amendment had the European Patent Office granted the '342 patent application on April 28, 1999, and only then with a disclaimer of the two probes (sequences 77 and 78) disclosed in the Cha PCT application.[368]

The '704 patent was issued on December 8, 1998 with neither the inventors nor their patent counsel ever having backed off their representation that they had invented the use of the genotype-specific sequences in the 5'UTR, including sequence ID No. 13.

Regardless of whether the Court believes this evidence meets the level of clear and convincing evidence, it certainly shows that there was a good faith basis for Abbott to assert and pursue its charge of inequitable conduct.[369] The final piece of the puzzle, Maertens'

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[365] Opinion and Order, 7/17/06, Dkt. No. 131, at 7.

[366] Opinion and Order, 7/17/06, Dkt. No. 131, at 8. The EPO also noted that the Cha PCT application was an enabling disclosure because "hybridization assays [were] well established techniques in the art." Declaration of Devanand J. Crease, Dkt. Nos. 56-57, Exh. A (European File Wrapper) at AB17890.

[367] Opinion and Order, 7/17/06, Dkt. No. 131, at 9.

[368] Opinion and Order, 7/17/06, Dkt. No. 131, at 9-10.

[369] In its 7/17/06 order, the Court concluded that "it is actually defendant that could not possibly have brought this counterclaim in good faith" and awarded Innogenetics' request for (footnote continued)

admission that it was Cha who invented this subject matter, came out at trial and shows that Innogenetics made an undeniably material misrepresentation to the Patent Office; its knowledge of the true facts and their likely effect on its application, coupled with its failure to say anything to the Patent Office, establishes the requisite intent.

VI. THERE IS NO OTHER BASIS FOR ENHANCING DAMAGES

A. Innogenetics' Brief, Filled With Misstatements, Demonstrates Far More About Its Own Misconduct Than Anything Abbott Did and Should Not Be Used As The Basis For a Ruling By The Court

As the evidence discussed above shows, all of Abbott's noninfringement and invalidity defenses, and its position on willfulness, were well supported by multiple pieces of solid, admissible evidence and established Federal Circuit precedent. Innogenetics avoids all that by trying to focus attention on the Court's various rulings, but the real measure is the underlying evidence – what actually happened. Abbott agrees with Innogenetics' view that this was never a close case,[370] but believes the case, as measured by the facts and evidence, were clearly in favor of Abbott, and not Innogenetics.

Also, in its eagerness to paint a situation ripe for enhancement, Innogenetics makes a series of demonstrably false statements that are not fact, are not evidence, or are merely argument that is unsupported by fact; and none of this fabrication should be considered as the Court makes its determination. Throughout this brief, several of these statements have been discussed at length. Another particularly striking false statement in Innogenetics' brief is that

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costs and attorneys fees . . . in an amount to be determined." Opinion and Order, 7/17/06, Dkt. No. 131, at 25. Abbott moved for reconsideration of this order, but it was denied. Opinion and Order, Dkt. 278, at 4. In light of the facts as they developed at trial, Abbott respectfully submits that these orders reached an unwarranted conclusion. In any case, Abbott should not be punished again pursuant to the current motion, when Innogenetics already made these same arguments earlier and prevailed.

"Abbott attempted to mislead the jury that the PTO was overburdened by patent applications and made a mistake."[371] This is absurd. The standard video shown by the Court explained that the PTO receives more than 300,000 applications and issues more than 150,000 patents each year, and showed stacks of applications in the main receiving room, as well as in the individual examiner's office, and explained that it might be some time before she got to a particular application because she must take them in the order received.[372] The video also stated that the "job of examining so many applications is very challenging."[373] In the context of invalidity, the video explained in effect that sometimes the jury is asked to decide whether the examiner might have made a mistake:

> whether the patent should have been allowed at all by the PTO. . . . [there] may be facts or arguments that the examiner did not consider . . . [or] of course, the possibility that mistakes were made or important information overlooked. Examiners have a lot of work to do and no process is perfect.[374]

The Court also explained to the jury "the basics of our patent system," including the fact that "[t]o be entitled to patent protection, an invention must be new, useful and nonobvious."[375] After expressly stating that the Court would "just reinforce that although you've heard that on the video," the Court went on to explain that "a patent cannot legally take away the right to use something that was already known before the invention was made or which was

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[370] Motion, at 27.

[371] Motion, at 26.

[372] Federal Judicial Center Video, http://www.fjc.gov/public/home.nsf/autoframe?openform&url_l=/public/home.nsf/inavgeneral?openpage&url_r=/public/home.nsf/pages/557.

[373] *Id.*

[374] *Id.*

[375] Trial Tr., 8/29/06, v. I, 23:11-12; 23:24-25.

obvious – or something that was obvious from what was already known. Thus, a patent will not be valid if it deprives people of the right to use old or known products or processes."[376] Abbott had, as we have seen, compelling invalidity arguments to make, as well as evidence that the patent examiner may not have reviewed, or fully understood, the Cha PCT reference, so it was perfectly reasonable for Abbott, as it was for the video and for the Court, to make statements regarding the possibility of the patent office making a mistake.

Other clear misstatements include that there was an "absence of *any* legal or factual basis for the positions advanced by Abbott,"[377] that "*[n]one* of the defenses raised in Abbott's pleadings proved to have even arguable merit,"[378] that there was an "absence of evidence for its reckless charge of inequitable conduct,"[379] that "Abbott's conduct throughout this trial can be fairly characterized as being 'in willful disregard' of the Court's orders,"[380] that "Abbott advanced . . . positions that it knew to be meritless based on the Court's claim constructions and rulings,"[381] that "Abbott increased the time and money required for Innogenetics to prosecute this case."[382] Innogenetics seems to feel no restraint whatsoever in presenting outrageous falsehoods to this Court and it should not be rewarded for this misconduct with enhancement or a finding of exceptionality based on them.

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[376] Trial Tr., 8/29/06, v. I, 23:25-24:7.

[377] Motion, at 1 (emphasis in original).

[378] Motion, at 1 (emphasis in original).

[379] Motion, at 2.

[380] Motion, at 2.

[381] Motion, at 6.

[382] Motion, at 17.

B. Abbott's Size And Financial Condition Do Not Justify Enhancement

Innogenetics phrased its argument with the wrong presumption. Enhancement of damages is intended as a punitive measure, and accordingly is not granted in the ordinary case. The relative size of the companies can be either a mitigating or ameliorating fact. See, e.g., *Kori Corp. v. Wilco Marsh Buggies and Draglines, Inc.*, 561 F. Supp. 512, 533 (E.D. La. 1982) (Exemplary damages "should not unduly prejudice the defendants' non-infringing business."); *Bott v. Four Star Corp.*, 229 USPQ 241, 254 (E.D. Mich.1985) ("[a] threefold increase in damages would severely affect [defendant's] financial condition."). Here, Abbott Molecular -- the entity that sells the accused HCV genotyping product -- is very similar in size to Innogenetics.[383] The absence of any gross disparity between the size of the companies -- which Innogenetics concedes[384] -- weighs against enhancement.

C. Duration of Misconduct Was Not Long, If It Even Occurred

Abbott took steps to ameliorate any harm to Innogenetics as soon as the verdict was read. For example, even though Abbott actively disputes the jury's findings, and has sought a new trial, it has offered to pay royalties into an escrow account pending a final resolution of this case. Accordingly, Abbott cannot be held to have engaged in "misconduct" for any great length. As noted previously, Abbott repeatedly and thoroughly investigated the scope of the patent and its application to Abbott's activities, and defended its actions based on the results of those investigations throughout trial. Abbott's good faith offer to begin paying royalties must be considered as an ameliorating factor weighing against enhancement of damages.

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[383] Trial Tr., 9/7/06, v. III, 32:3-9.

[384] Motion, at 31-32.

D. Abbott Had No Motivation to Harm Innogenetics

Innogenetics argues that because it competed with Abbott in the marketplace, Abbott had a per se motivation to harm. But Abbott had other business dealings with Innogenetics.[385] And Abbott had a practice of licensing the technology it needed, even from its potential or actual competitors. For example, even though it meant its profits would be cut by 40%, Abbott agreed to license technology for the HCV products from Chiron, Roche, and two smaller companies. This is not an action taken by a company that perceived competitors as objects to harm. The facts show that Abbott in fact had no motivation to harm Innogenetics, and even if mere competition could be deemed motivation, its evidence of good faith dictates that this factor weigh against enhancement.

E. Abbott Did Not Attempt To Conceal Any Misconduct

Innogenetics makes no argument that Abbott concealed any information related to its product. Dr. Galloway from Abbott actually had conversations with people at Innogenetics and explained to them the basis for his belief that Abbott did not need to license the '704 patent.[386] That frankness was echoed by Mr. Michael when he met with Innogenetics' CEO, and similarly explained why Abbott would decline the offered license.[387]

In reality, Innogenetics was the party that attempted to conceal its intentions. It initially offered licenses for some, but not all, of its patents -- the '704 was not mentioned by Innogenetics until a full year after its first contact with Abbott.[388] Indeed, Innogenetics

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385 Trial Tr., 9/6/06, v. II, 62:18-63:9.

386 Trial Tr., 9/7/06, v. III, 18:14-20.

387 Trial Tr., 9/7/06, v. III, 19:14-18.

388 DX 509; PX 1047, Gross Decl., Ex. E, H.

affirmatively disavowed any intention to sue Abbott - possibly postponing Abbott's decision to formalize the legal opinions it had received in readiness for trial.

This factor not only does not weigh in favor of enhancement, it underscores the breadth of action Abbott took in good faith as it dealt with Innogenetics from its first notice of the '704 patent through trial.

VII. THERE IS NO BASIS TO FIND THIS CASE "EXCEPTIONAL"

Attorneys' fees may be awarded under 35 U.S.C. §§ 284-85 only in "exceptional" cases, such as those that are unnecessary and outcome-certain. *Kloster Speedsteel AB v. Crucible Inc.*, 793 F.2d 1565, 1580-81 (Fed. Cir. 1986). Such an award is appropriate only where there has been fraud or lack of good faith. *Arbrook, Inc. v. Am. Hosp. Supply Corp.*, 645 F.2d 273-279 (Fed. Cir. 1981) ("The purpose of § 285 is to prevent gross injustice and an award under that statute requires an unambiguous showing of extraordinary misconduct."). It is not bad faith to argue and lose defenses of invalidity and non-infringement. *Kalman v. Berlyn Corp.*, 914 F.2d 1473 (Fed. Cir. 1990). It is also not bad faith to litigate vigorously and aggressively, nor to advance numerous objections and motions of varying degrees of merit, so long as each is reasonable and non-frivolous. *Knorr-Bremse Systeme Fuer Nutzfahrzeuge GmbH v. Dana Corp.*, 372 F. Supp. 2d 833, 851-52 (E.D. Va. 2005); *Oscar Mayer Foods Corp. v. Conagra, Inc.*, 869 F. Supp. 656, 667-68 (W.D. Wis. 1994).

For all the reasons stated above, Abbott had a good faith basis to pursue each of its defenses, and attorney's fees should not be awarded.

CONCLUSION

For all the reasons stated above, Innogenetics' motion for enhanced damages and attorney's fees should be denied.

ABBOTT LABORATORIES

Dated this 10th day of October, 2006 By: *s/Gabriel S. Gross*

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